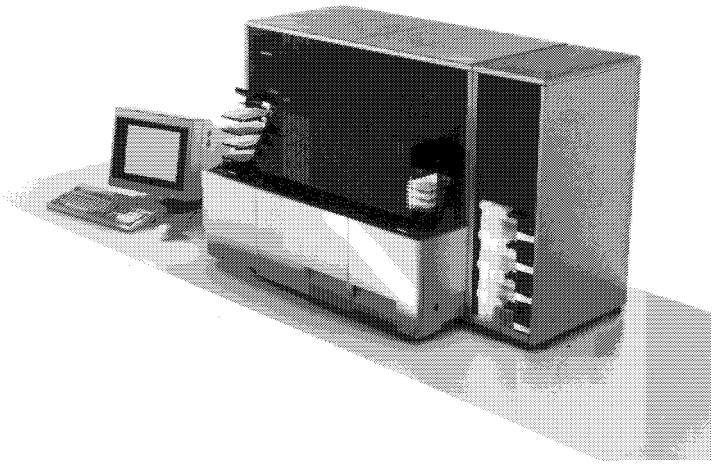
Microlab F.A.M.E.

USER MANUAL

Version 2.0



Important Notice

This manual may not be used or reproduced in any way whatsoever without the express written consent of Hamilton Bonaduz AG.

Copyright © 1995, 1996, 1997, 1998, 1999 Hamilton Bonaduz AG, All Rights Reserved.

Microlab is a registered trade mark of Hamilton Bonaduz AG.

IBM, OS/2, DATABASE 2 and DB2 are registered trademarks of International Business Machines Corporation.

MICROTITER is a registered trademark of Dynatech Laboratories.

P/N 610520/02 05/01

Master Table of Contents

1 - ML F.A.M.E. Overview 1

Cook Book - Chapter 2 to 8

2 - Cook Book Introduction 25
3 - ML F.A.M.E. Methods 27
4 - Daily Work Routine.....41
5 - Test Results & ML F.A.M.E. Traces.....55
6 - Instrument Status 63
7 - ML F.A.M.E. Verification.....65
8 - ML F.A.M.E. Maintenance 69

Reference Guide - Chapter 9 to 17

9 - Reference Guide Introduction.....81
10 - ML F.A.M.E. Methods 83
11 - Daily Work Routine.....105
12 - Test Results & ML F.A.M.E. Traces.....129
13 - ML F.A.M.E. Functions & Requirements 137
14 - ML F.A.M.E. Verification.....147
15 - ML F.A.M.E. Maintenance 169
16 - Technical Specifications.....183
17 - Troubleshooting & Error Handling 199

Appendices - A1 to A8

A1 - Error & Trace Codes Messages.....213
A2 - Glossary 237
A3 - Frequently Asked Questions 247
A4 - Anomalies 249
A5 - Forms 251
A6 - News Letters 261
A7 - User Manual Update Information 263
A8 - Index 265

Chapter 1 ML F.A.M.E. Overview

Table of Contents

1.1 - About the Microlab F.A.M.E. 2
1.1.1 - Basic Concepts 2
1.2 - Using This Manual....3
1.2.1 - User Manual Symbols 3
1.3 - ML F.A.M.E. Components 4
1.3.1 - The ML F.A.M.E. Instrument 4
1.3.2 - The ML F.A.M.E. Workstation 9
1.4 - General Information 12
1.4.1 - Warranty....12
1.4.2 - Ordering Information 13
1.4.3 - Definition of Terms....17
1.4.4 - Safety Precautions and Hazards....17

1.1 About the Microlab F.A.M.E.

1.1.1 Basic Concepts

The Microlab F.A.M.E. (ML F.A.M.E.) is a diagnostic instrument used to analyze blood samples for the presence of certain biological elements.

This analysis is performed using the *ELISA* (Enzyme Linked Immuno Sorbent Assay) testing process. This process requires samples to be manipulated in various ways, i.e. incubating, washing, dispensing, mixing, photometric measurement, etc.

The ML F.A.M.E. has been developed with a modular design, incorporating all functions necessary to perform these sample manipulations.

The test process is controlled by a highly developed software pakkage allowing:

- ❒ Simultaneous processing of tests from different manufacturers.
- ❒ Easy adaptation of various tests using the ML F.A.M.E. Method Editor.
- ❒ Automatic schedule optimization and work list visualization.
- ❒ Full traceability and documentation of sample processing and of individual instrument functions.

1.1.1.1 Intended Use

The intended use of the ML F.A.M.E. is to process microplate based *ELISA* assays for screening blood and blood products for the presence of any blood-borne pathogen, primarily in screening centers, plasma centers, hospitals, public health centers and reference laboratories.

1.1.1.2 ML F.A.M.E. Operator

Any persons operating the ML F.A.M.E. and ML F.A.M.E. workstation must have attended a certified training course. Any departure from the following texts could lead to erroneous results or ML F.A.M.E. malfunction.

1.2 Using This Manual

This manual has been developed for use with ML F.A.M.E. version 2.0 and should not be used with any other software version unless previously announced by the supplier.

The documentation set has been designed to allow various levels of ML F.A.M.E. operator to access the required information as they progress in their knowledge of the environment.

This has been achieved using a three part structure:

❒ **ML F.A.M.E. Overview**

The ML F.A.M.E. Overview gives general information about the ML F.A.M.E., its computer environment, functions and intended use.

❒ **Cook Book**

The Cook Book defines the ML F.A.M.E. operator related tasks in a step-by-step guide.

In each section there is an introduction explaining the task then a table structure defining a question and then an explanation of the procedures needed to achieve this task.

Where necessary there are “Notes” and “Attention” paragraphs to bring certain information to the ML F.A.M.E. operator. These paragraphs are positioned in the left column to avoid any interruption in the flow of the step by step process.

❒ **Reference Guide**

The Reference Guide gives full technical information on all functions of the ML F.A.M.E. and is designed to be used as both support for the Cook Book (through extensive cross referencing) and as a stand alone reference work.

“Notes” and “Attention” paragraphs, similar to those used in the Cook Book are also used in the Reference Guide.

1.2.1 User Manual Symbols

ATTENTION **NOTE**

ATTENTION: Any special problems, warnings or important information will be accompanied by this symbol. Read these carefully as they can easly help to understand particular issues.

NOTE: This is used to give information to the ML F.A.M.E. operator that is useful but not essential to the task at hand. Read these carefully as they can easly help to understand particular issues.

1.3 ML F.A.M.E. Components

The ML F.A.M.E. consists of two parts:

- ❒ The ML F.A.M.E. Instrument.

  and

- ❒ The ML F.A.M.E. Workstation (including ML F.A.M.E. software).

1.3.1 The ML F.A.M.E. Instrument

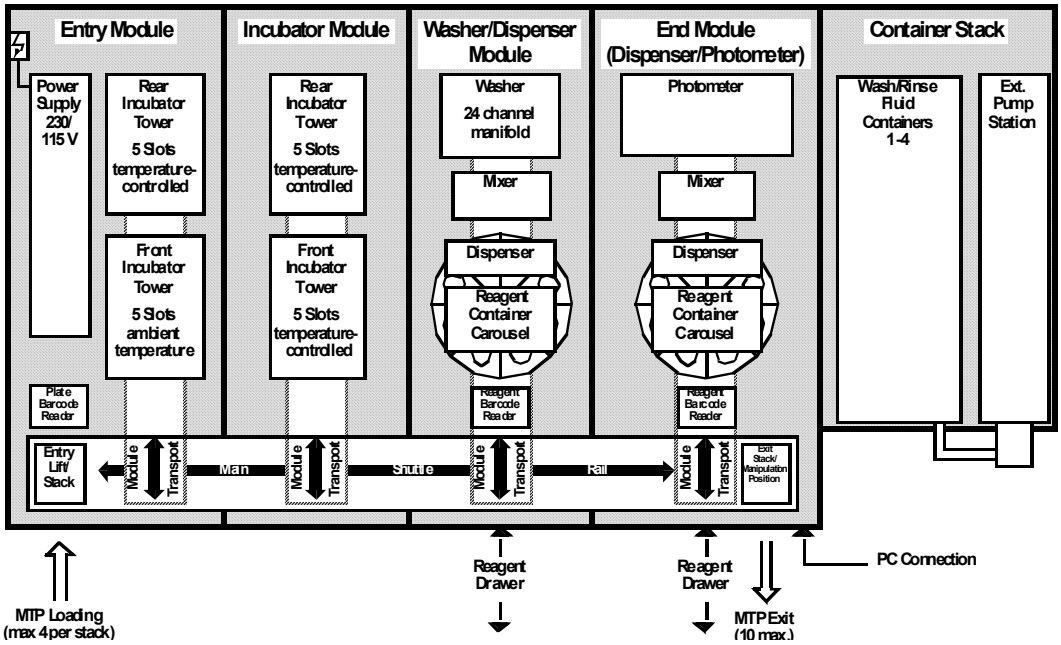


Figure 1.1 16/20 configuration (top view)

The primary functions of the ML F.A.M.E. include:

- ❒ Positive plate identification.
- ❒ Incubation (temperature-controlled or ambient).
- ❒ Washing (with liquid level detection).
- ❒ Dispensing (including positive reagent identification and liquid level detection).
- ❒ Photometric measurement.

1.3.1.1 Configurations

All instrument configurations consist of a combination of four different modules.

- ❒ Entry Module - 10 incubation slots
- ❒ Incubator Module - 10 incubation slots
- ❒ Washer/Dispenser Module with External Pump Station
- ❒ End Module

These four basic modules connected to the chassis, plus a container stack, complete the basic instrument configuration 16/20 - 16 reagent positions and 20 incubator slots.

By adding an extra incubator module and/or an extra washer/dispenser module to the chassis, the following three instrument configurations are also possible:

- ❒ 16/30 - 2 incubator modules giving 30 incubation slots
- ❒ 24/20 - 2 washer/dispenser modules giving 24 reagent positions
- ❒ 24/30 - 2 incubator modules and 2 washer/dispenser modules

Upgrade from one configuration to a higher specification instrument is possible in the field.

1.3.1.2 Entry Module

The main functions of the Entry Module are:

- ❒ Loading of the plates
- ❒ Plate barcode reading (positive plate identification)
- ❒ Incubation

The Entry Module consists of the following components:

1.3.1.2.1 Entry Section

The entry platform is used to load plates onto the instrument. All plates are placed manually onto the entry platform.

There are two ways of loading plates:

1 Place a single plate directly onto the entry platform.
2 Place an entry stack (which accommodates up to 4 plates) onto the entry platform.

1.3.1.2.2 Plate Barcode Reader

The function of the plate barcode reader is to identify barcodes on the plates. Barcode information is also used to select the test method and or kit lot to be used.

After reading, the plate is transported automatically, according to the selected method, to the defined modules for processing, e.g. incubator, washer, etc.

1.3.1.2.3 Incubators

NOTE
Slots within the same incubator tower cannot be individually programmed. However, each slot is individually temperature-controlled.

The Entry Module contains two incubator towers each with 5 incubation slots.

The front tower is used for ambient temperature incubation only.

The rear tower is used for ambient temperature or for temperature-controlled incubation.

The temperature can be set between ambient and 45°C. A plate can be loaded individually into each slot.

1.3.1.2.4 Power Distribution

The power supply for all the modules is built into the Entry Module. The mains power connector and the on/off switch are located on the left hand side of this module towards the rear.

The primary and secondary protection switches (circuit breakers), and the voltage selector switch (230/115V) are also located in this area, behind the instrument side panel.

1.3.1.3 Incubator Module

NOTE
Slots within the same incubator tower cannot be individually programmed. However, each slot is individually temperature controlled.

The Incubator Module contains two temperature-controlled incubator towers each with 5 incubation slots.

The temperature of both towers is programmable up to 70°C (maximum allowed temperature difference between the two towers: 25°C).

An individual plate can be loaded into each incubator slot.

1.3.1.4 Washer/Dispenser Module

The main functions of the Washer/Dispenser Module are:

- ❒ Plate washing
- ❒ Dispensing of reagents
- ❒ Mixing (shaking of plates)

Washer/Dispenser Modules consist of the following components:

1.3.1.4.1 Washer

The washer comprises a 24-channel manifold consisting of 3 rows of 8 needles. Each of the 24 wells is washed simultaneously.

An adjustment of the manifold liquid level detection system is executed automatically during every cold start of the system.

Each needle has liquid level detection. If a well cannot be properly washed, the liquid level detector produces an error which is documented as a message in a trace file.

Three different wash solutions (up to 3 liters each) and one rinse fluid (up to 3 liters) can be loaded into the container stack situated next to the End Module. All wash fluid containers have liquid level detection. All wash functions and liquid definitions are programmable by the user software in the Method Definition. For example:

- ❒ Wash mode
- ❒ Number of wash cycles
- ❒ Soak time
- ❒ Volume of liquid
- ❒ Solution name

1.3.1.4.2 Waste Container

The waste container holds the fluid that is aspirated from the plates during washing and has a capacity of 10 liters. A liquid level detector is incorporated in the waste cap. When the container is full, a message appears on the workstation screen. Exchanging of waste containers is possible without interrupting instrument operation.

1.3.1.4.3 External Water Separator

The external water separator holds fluid that is expelled from the venting tube.

1.3.1.4.4 Dispenser

A single channel dispenser, using disposable syringes and reagent containers dispenses the required reagents into the plates.

Carry-over is eliminated by the use of Hamilton Reagent Container Systems with dedicated syringes for each reagent liquid.

Liquid Level Detection is used during the reagent's distribution process.

1.3.1.4.5 Reagent Container System

Each Reagent Container System consists of:

- ❒ A reagent container
- ❒ A dedicated disposable syringe
- ❒ A barcode label

In total, 8 reagent container systems can be positioned in segments on the reagent container carousel. The carousel is then placed into the reagent drawer.

Several reagent container carousels can be utilized. Single reagent container systems or complete reagent container carousels can be exchanged and kept in a refrigerator.

1.3.1.4.6 Reagent Container Identification

Each reagent container is identified by a clear text label and a barcode. A barcode reader located in each reagent drawer identifies the reagents.

Barcodes are supplied for containers. You may use other barcode labels providing that they comply with ML F.A.M.E. specifications, see Reference Guide Section 16.3.2 on page 193.

1.3.1.4.7 Mixer

The mixer is used for horizontal shaking of the plate in the lengthwise direction. The mix intensity and the mix time are programmable.

1.3.1.5 End Module

The main functions of the End Module are:

- ❒ Reagent dispensing
- ❒ Photometric measurement
- ❒ Mixing (shaking of the plate)

The Exit Stack is also located in this module allowing plates to be removed from the instrument.

The End Module comprises the following components:

1.3.1.5.1 Dispenser

The function of the dispenser is the same as the one in the Washer/Dispenser module.

1.3.1.5.2 Mixer

The mixer is identical to the one in the Washer/Dispenser module.

1.3.1.5.3 Photometer

The photometer has 8 measuring channels (i.e. 8 wells can be measured simultaneously) and one additional reference channel. There are 5 filters incorporated with the following wavelengths:

- ❒ 340 nm
- ❒ 405 nm
- ❒ 450 nm
- ❒ 492 nm
- ❒ 620 nm

Up to 8 filters can be used. These may have wavelengths ranging from 340 nm to 750 nm.

The following parameters are programmable via the user software:

- ❒ Measurement wavelength
- ❒ Reference wavelength

1.3.1.5.4 Exit Stack

The exit stack is where the instrument stores finished plates (i.e. plates which have had all processing steps performed on them). From here the plates can be removed and disposed of.

Approximately 10 plates can be stored in the exit stack. Bristles hold the plates in place in the exit stack. A sensor controls the exit status.

If the stack is nearly full, a warning message is displayed by the user software. Plates can be removed at any time without interrupting processing.

1.3.2 The ML F.A.M.E. Workstation

The ML F.A.M.E. Workstation is an IBM compatible personal computer (PC), to the specification listed in section 1.3.2.1 en la página 1-9, running the IBM operating system OS/2 WARP with IBM's DB2/2 and version 2.0 of the ML F.A.M.E. software.

1.3.2.1 The Computer

The specification of the personal computer required for use with the ML F.A.M.E. is listed in Reference Guide Section 16.4 on page 196 and it is highly recommended to use a system as similar as possible.

1.3.2.2 The Operating System

An operating system is a software application allowing the system operator to access installed software and to write and read information to a storage device, i.e. floppy or fixed disk.

This software application has been designed and created to run with IBM's OS/2 operating system (WARP). It also utilizes IBM's data storage retrieval system DB2/2.

OS/2 is a Graphic User Interface (GUI) operating environment which means the ML F.A.M.E. operator can access the required functions using an object oriented control method, i.e. to access a function the ML F.A.M.E. operator will physically select the command for that function using a pointing device, e.g. a mouse.

For further information on using OS/2 and DB2/2 please consult the supplier or the documentation supplied with the product.

1.3.2.3 The ML F.A.M.E. Software

NOTE
The standard Microlab F.A.M.E. software does not include the Active Kit Lot Check and Sample and Reagent Addition Monitoring (SRAM) features. If Hamilton users need these features, authorization from Hamilton and OCD is required for blood banks in specific territories. Please contact the Product Manager at Hamilton Bonaduz to obtain the special disk set.

The ML F.A.M.E. software is an application with various access rights assigned to the various levels of ML F.A.M.E. operator giving them software control on a need-to-use basis.

Main features of the software include:

- ❒ Full operations tracing (ML F.A.M.E. operator, ML F.A.M.E. software and ML F.A.M.E. functions and actions).
- ❒ Full sample tracing (from entire plates to individual wells).
- ❒ Temporary storage of processed plates' data.
- ❒ Method definition and editing.
- ❒ Scheduling with re-scheduling options.
- ❒ Graphical representation of daily work routine.
- ❒ Extensive error handling and recovery routines.
- ❒ Complete instrument maintenance and verification procedures.

1.3.2.4 Installation Options

ATTENTION
For further information on installation please see the separate Installation Guide. It is the responsibility of the laboratory manager which installation options are selected.

During the installation procedure for the ML F.A.M.E. software a number of features exist allowing the customizing of the installation.

The installation options are as follows:

- ❒ **Verification Restrictive:**
  With this option selected the ML F.A.M.E. operator will be prompted when trying to start a run, if there are verification procedures required. It is not possible to run ML F.A.M.E. if the required verification for any module is not completed. The only exception is if the ML F.A.M.E. operator is asked whether or not to run verification on an incubator slot and answers "no" then that slot will be locked, although a run can be started.

ATTENTION
With this option on it is possible to operate an "un-verified" instrument.

- ❒ **Verification Non-restrictive:**
  With this option selected the ML F.A.M.E. operator will be prompted when trying to start a run, if there are verification procedures required. It is still possible to use ML F.A.M.E. modules if the required verification for that module is not completed, e.g, if the ML F.A.M.E. operator is asked whether or not to run verification on an incubator slot and answers "no" then that slot will be not locked, however, the error status of a test will be set to trace and all test traces will contain a warning indicating the required function was not verified when requested.

- ❒ **Plate Access Off:**
  With this option selected the ML F.A.M.E. software must find the pipetting information on the first try or else the plate will not be accepted for processing. No other options are allowed.

ATTENTION

Please ensure that the correct sample barcodes are entered. Sample barcodes from the plate barcode file are write protected.

ATTENTION

Please ensure that the correct kit lot data is defined in the kit lot editor.

ATTENTION

Please ensure that the default users are deleted and the correct lab specific users and access rights are defined.

❒ **Plate Access On:**
With this option selected the ML F.A.M.E. software will allow the ML F.A.M.E. operator to process plates when no pipetting information is found. Options include retry or searching for the barcode information along a path, using an editor to include or exclude wells or to enter the well barcodes after plate loading.

❒ **Active Kit Lot Check:**
With this option selected the master kit lot number included in the plate barcode or in the pipetting file will be checked against the defined one. The kit lot file must be provided by the higher system, no access is given to the editor.

❒ **Kit Lot Documentation:**
With this option selected the ML F.A.M.E. operator will have access to the Kit Lot Editor allowing editing or creating of kit lot information file. However, the defined kit lot will be documented, but no check is made of the loaded lot.

❒ **User Access Editor Off:**
Disables the **User Access Editor**.

❒ **User Access Editor On:**
Enables the **User Access Editor** where it is possible to establish a list of ML F.A.M.E. operators and their security level.

1.4 General Information

1.4.1 Warranty

HAMILTON warrants this product to be free of defects in material and workmanship for a period of 12 months from the date of delivery.

HAMILTON or an authorized HAMILTON representative will repair or replace, at its option and free of charge, any product that under proper and normal use proves to be defective during the warranty period.

HAMILTON shall in no event be liable or responsible for any incidental or consequential damage, either direct or contingent.

HAMILTON consumable products such as syringes, valves, tubing, disposable tips, etc. are warranted to be free of defects in material and workmanship at the time of delivery only.

This warranty shall not apply if:

1 the product has not been operated in accordance with the ML F.A.M.E. operator manual
2 the product is not regularly and correctly maintained
3 the product is not maintained, repaired or modified by a HAMILTON authorized representative or ML F.A.M.E. operator
4 parts other than original-HAMILTON parts are used
5 the product and parts thereof have been altered without written authorization from HAMILTON
6 the product is not returned properly packed in the original HAMILTON packaging

HAMILTON reserves the right to refuse to accept the return of any product that has been used with radioactive or microbiological substances, or any other material that may be deemed hazardous to employees of HAMILTON. Such a product has to be properly decontaminated and marked.

HAMILTON endeavors to provide prompt and satisfactory service.

1.4.2 Ordering Information

Instruments

Part No.	Description
146 000	Microlab F.A.M.E. 16/20
146 001	Microlab F.A.M.E. 16/30
146 002	Microlab F.A.M.E. 24/20
146 003	Microlab F.A.M.E. 24/30

Disposables for Microlab F.A.M.E.

Part No.	Description
147 624	Wash Fluid Container
147 930	Reagent Container Set (8 pcs.)
147 931	Disposable Syringe Set (8 pcs.)
147 933	Reagent Barcode Label Set (52 pcs.)
281 110	Manifold Plug
281 153	Sterile Filter
281 242	Microlab™ Detergent & Disinfectant Kit
281 243	Microlab™ Disinfectant Spray Kit
281 245	Microlab™ Disinfectant Starter Kit

Accessories for Microlab F.A.M.E.

Part No.	Description
281 107	Waste Container
147 660	Entry Stack
147 179	Reagent Container Carousel
148 309	Washer Manifold complete
235 524	Filter Strip
147 256	Filter Case
147 936	Manifold Cleaning Set
148 333	Spillage Tray
230 005	Check Plates for Cold Start Maintenance
146 373	Substitute Plug
146 385	Computer Cable
255 634	Reagent Labels Drawer
255 653	Label Warning PC
148 417	External Water Separator
148 335	Waste Cap
610 520	User Manual (English)
230 006	Upgrade Kit V2.0 for 16/20 or 16/30
230 007	Upgrade Kit V2.0 for 24/20 or 24/30

Barcodes for Wash System

Part No.	Description
255 734	External Pump Station - Washer 1
255 735	External Pump Station - Washer 2
255 736	Ortho Specific Wash Fluids - Washer 1
255 737	Ortho Specific Wash Fluids - Washer 2
255 738	Maintenance Fluids - Washer 1
255 739	Maintenance Fluids - Washer 2
255 740	Generic Wash Fluids

Verification Kit

Part No.	Description
148 381	Verification Kit
148 383	Washer/Dispenser Verification Kit
148 405	Incubator Check Plate

Modules

Part No.	Description
148 301	Expansion 16/20 to 16/30 configuration
148 302	Expansion 16/20 to 24/20 configuration
148 303	Expansion 16/20 to 24/30 configuration
148 304	Expansion 16/30 to 24/30 configuration
148 320	Expansion 24/20 to 24/30 configuration

Photometer Filters for Microlab F.A.M.E.

Part No.	Description
235 511	340 nm
235 504	405 nm
235 505	450 nm
235 506	492 nm
235 509	620 nm

Optional Filters for Microlab F.A.M.E.

Part No.	Description
235 521	570 nm
235 525	610 nm
235 510	690 nm
-	Other filters available on request.

Microlab F.A.M.E. Software

Part No.	Description
910 034	User Software (English) including firmware

1.4.3 Definition of Terms

The terms ***Microplate*** and ***MTP*** are the same and will otherwise be referred to as ***plate***.

The term ***ML F.A.M.E.*** refers to the Microlab F.A.M.E. instrument.

The term ***ML F.A.M.E. software*** refers to the Microlab F.A.M.E. user software.

The term ***ML F.A.M.E. database*** refers to the Microlab F.A.M.E. database.

The term ***ML F.A.M.E. workstation*** refers to the PC running the ML F.A.M.E. software and the cable connecting this to the ML F.A.M.E..

The term ***ML F.A.M.E. operator*** refers to the person who operates the ML F.A.M.E. and ML F.A.M.E. software.

The term ***"Test Kit"*** refers to the package containing all necessary components for one or several assays of a kind.

1.4.4 Safety Precautions and Hazards

Read the following safety notices very carefully before using the ML F.A.M.E..

1.4.4.1 General Precautions

1 When using the ML F.A.M.E., good laboratory working practices should be observed. Suitable protective clothing, safety glasses and protective gloves should be worn, particularly when dealing with a malfunction of the instrument where the risk of contamination from spilled liquids exists.

2 Only certified technicians are authorized to perform mechanical maintenance on the ML F.A.M.E..

3 While extensive efforts have been made to ensure error-free test processing and general system security, any manual manipulation of ML F.A.M.E. data files or other information pertaining to ML F.A.M.E. functions can result in erroneous test results or ML F.A.M.E. failure.

4 During instrument operation, do not place hands in the way of moving parts or microplates. Do not touch the incubator towers with bare hands as these may cause burns (max. temp: 70°C).

5 Smoking and eating in the vicinity of the instrument and in rooms in which samples or reagents are handled is forbidden (see also warning notices and precautionary measures in the test kit pakkage inserts).

6 During operation, the instrument should be shielded from direct sunlight and intense artificial light.

7 Nothing should be attached to a microplate when it is loaded into the instrument (except one barcode).

8 Each plate barcode must be unique.

9 Ensure that barcode labels do not protrude above or below the level of the surface of the microplates.

10 Microplates must be placed in the entry stack or on the entry platform such that well A1 is in the front left position.

11 Under normal operating conditions microplates should only be loaded into the instrument via the entry platform or entry stack and removed via the exit stack. Only when specifically instructed by the ML F.A.M.E. software may plates be directly placed in or removed from the instrument.

12 Do not swap plates on the entry stack after loading (i.e. after pressing the load button).

13 Do not open the transparent cover unless instructed by the user software as processing may be interrupted leading to aborted plates. An open transparent cover causes the main shuttle to stop (i.e. the part that moves plates from module to module) but all functions within modules continue (moving parts).

14 The pause button should generally not be pressed unless instructed by the ML F.A.M.E. software or in case of an emergency stop situation, as plate processing may be interrupted leading to aborted plates. Carefully follow the on screen instructions.

15 Pay close attention to all instructions and parameters given in test kit package inserts when programming test methods for the ML F.A.M.E. and when preparing said test kits for use with a test.

16 A newly programmed test method should first be run on the system using deionized water containing 0.9% NaCl in place of all reagents and wash solutions, to verify correct test definition and operation prior to the verification/validation of the method. This run should be overseen by the method programmer.

17 Only original ML F.A.M.E. specific parts and tools may be used with the ML F.A.M.E., i.e. syringes, reagent containers, wash containers and waste containers.

18 Never lift a fully installed (assembled) instrument from one place to another. It must first be dismantled (only by an authorized technician) and then reinstalled in the new work place.

19 The instrument weighs in excess of 220 kg. Necessary precautions should be taken when carrying individual modules and when transporting the instrument.

20 After repair/service/module exchange, the instrument should be verified using the verification kit.

21 For reasons of data security and integrity it is recommend to use the system with an uninterruptable power supply (UPS) since a loss of power may cause data to be lost or corrupted.

1.4.4.2 Electrical Safety Precautions

ATTENTION

Before connecting and switching on the instrument, check the setting of the voltage selector switch and if necessary, switch

Severe damage will occur to an instrument set to 115V which is connected to a 230V mains electricity supply!

Before removing a mechanical or electrical component, the instrument must first be switched off and disconnected from the mains electricity supply and PC.

1.4.4.3 Hazards

Location of warning and attention labels and general location information:

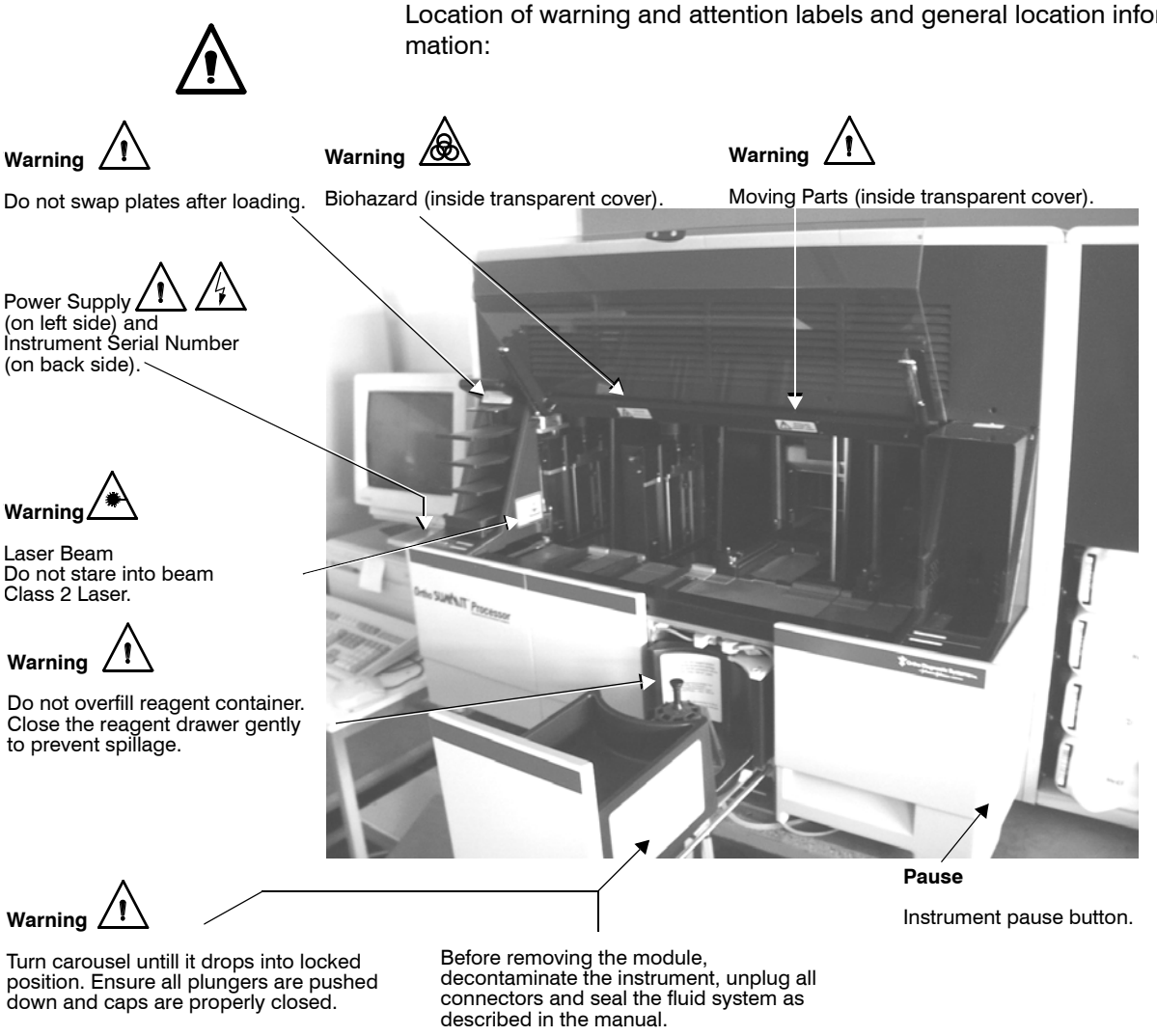
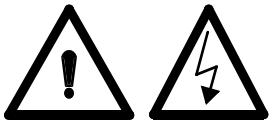

Warning
Do not swap plates after loading.
Warning
Biohazard (inside transparent cover).
Warning
Moving Parts (inside transparent cover).
Power Supply
(on left side) and
Instrument Serial Number
(on back side).
Warning
Laser Beam
Do not stare into beam
Class 2 Laser.
Warning
Do not overfill reagent container.
Close the reagent drawer gently
to prevent spillage.
Pause
Instrument pause button.
Warning
Turn carousel untill it drops into locked position. Ensure all plungers are pushed down and caps are properly closed.
Before removing the module, decontaminate the instrument, unplug all connectors and seal the fluid system as described in the manual.

Figure 1.2 Warning Labels and general locations

Explanation of warning and attention labels



Power Connection:

Connect only to earth grounded outlet
115V~/...A 60Hz
230V~/...A 50Hz

Warning Symbols

General Warning

Danger High Voltage

Bio-Hazard

Danger Laser

If the instrument becomes contaminated with liquids, it should be cleaned in accordance with the maintenance procedures, see Reference Guide Section 15.1.6 on page 173.

Certain parts of the instrument are **biohazardous**. Observe and carry out the maintenance procedures, see Reference Guide Section 15.1.6 on page 173 paying particular regard to cleaning and decontamination.

Do not use disinfecting materials which contain hypochlorite (Javelle water, Chlorox) or bleaching fluids.

Failure to observe and carry out the maintenance procedures may impair the reliability and correct functioning of the instrument.

Wear gloves when exchanging the sterile filter and handling the venting tube as any liquid which is released is **biohazardous**.

Any surfaces on which liquid is spilled must be decontaminated.

1.4.4.4 Software Precautions

The ML F.A.M.E. Workstation should not be used for running any other applications (programs) except those described in 1.3.2 en la página 1-9.

The ML F.A.M.E. Workstation date and time must not be changed while the instrument is running tests or while the user software is running or being started up, otherwise trouble-free operation cannot be guaranteed.

The operating system (OS/2) and database (DB2/2) functions are optimized to suit the instrument configuration. Changes to the setup can impair the operational reliability and data security of the system.

Only the ML F.A.M.E. software may be used to control the ML F.A.M.E..

When running the system 24 hours a day, shut down and restart the system once a day in order to re-calibrate the washer, photometer, etc. and also carry out cold start maintenance.

The ML F.A.M.E. operator is responsible for the security of communication between the ML F.A.M.E. and any host computer. The ML F.A.M.E. system creates result files but does not provide the specific communication protocols to ensure reliable and safe transmission of result files.

Chapter 2 - 8 Cook Book

Cook Book Sections

2 - Cook Book Introduction 25
3 - ML F.A.M.E. Methods 27
4 - Daily Work Routine.....41
5 - Test Results & ML F.A.M.E. Traces.....55
6 - Instrument Status 63
7 - ML F.A.M.E. Verification.....65
8 - ML F.A.M.E. Maintenance 69

Chapter 2 Cook Book Introduction

The purpose of the cook book is to give a step-by-step guide to the day-to-day operation of the ML F.A.M.E. and the ML F.A.M.E. software version 2.0.

Each section consists of an introduction explaining the basic principles being covered, then a step by step guide to each task in a tabulated two column format.

❒ Column 1 - The Task.

❒ Column 2 - The Procedure.

Any additional information for the operator's attention is displayed in the left margin as either a "Note" or an "Attention".

A certain amount of basic computer understanding will be assumed throughout these examples and most will assume that a valid ML F.A.M.E. operator with the necessary access rights is logged in to the ML F.A.M.E. workstation.

In trying to avoid long-winded explanations and examples, common information, i.e. explanations of common fields, push-buttons, etc., of a repetitive nature has been omitted (unless applicable) and is explained in the Reference Guide section of this document set.

Special information, directly related to the task being explained (but not a step in the procedure) like warnings and notes being brought to the attention of the user are displayed in the left margin of this document to avoid breaking the flow of the examples.

Chapter 3 ML F.A.M.E. Methods

Table of Contents

3.1 - Overview....28
3.1.1 - Method Definition....28
3.1.2 - Documenting a Test Run....37
3.1.3 - Method Management....38

3.1 Overview

A method is a structured group of definitions, stored electronically, which enables an Immunoassay test to be performed on the ML F.A.M.E. and includes plate layout information, processing step definitions and documentation criteria for the test.

For further information on methods see Reference Guide Section - 10.1 on page - 84.

3.1.1 Method Definition

The following section defines the creation of a method as described in a Test Kit Manufacturer's Package Insert. Even though it is not generally possible to create or edit in any way, this is explained to clarify the structure of the methods.

Example Information Required To Program A Method

Method Name: Example ELISA.

Manufacturer: Example Company.

Parameter: Hepatitis B Antigen.

NOTE
Only wash solutions that are specified as suitable by the test kits' manufacturer should be used.

Test Kit: The Test Kit contains all necessary reagents except wash and stop solution, which is available separately. Note that the substrate solution should be used within 60 mins of preparation.

Ambient Temperature Conditions: 15 - 30°C

NOTE
Plate dimensions are not normally included in the package insert and must be measured by hand with the vernier caliper. This is to prevent possible spillage, contamination, or errors during wash and dispense steps. The dimensions shown are given as an example only.

Plate Dimensions:

Plate Length: 127.5 mm

Plate Height: 14.5 mm

Well Diameter: 6.6 mm

Well Depth: 11.4 mm

Well Shape: Flat

Strip Direction: A - H

Sample Filling Direction: A - H

Assay Procedure:

1 Dispense 50 µl of conjugate solution into each well of the plate except the blank.

Example Information Required To Program A Method *(CONTINUED)*

2 Pipette controls and samples as follows:

- A1 Substrate Blank (BL)
- B1, C1 & D1 (100 µl) - Negative Control (NC)
- E1 & F1 (100 µl) - Positive Control (PC)
- G1 & H1 keep empty (##)
- Pipette all remaining wells with 100 µl of the SAmples to be tested

3 SRAM (measuring filter - 450 nm) see Reference Guide Section - 10.2.3.3 on page - 95 for further information on this step.

4 Place the plate in the incubator as soon as possible, max. 30 min after completion of the sample distribution step.

5 Incubate at 37 +/- 1°C for 30 +/- 5 min.

6 Wash plate 5 times: completely aspirate the liquid from all wells and fill the wells with 370 µl of wash solution. The washing solution should be allowed to remain for 20 seconds in the wells before being removed.

7 Dispense 200 µl of the substrate solution into each well.

8 SRAM (measuring filter - 450 nm).

9 Incubate the plate at room temperature for 30 +/- 2 min.

10 Reidentify the plate.

11 Stop the reaction by adding 50 µl 2 mol/l sulphuric acid to each well.

12 Shake the plate for 10 seconds.

13 Read the optical density at 492 nm, with 620 nm as the reference wavelength.

The following table defines, step by step, how to create this method as per the above method programming information.

Table 3.1.1.1 - Method Definition Process

To...		Do This...
Create a method	**.1)**	Select the **New** menu choice from the **Methods** pull-down menu. The **Method - New** dialog box is then displayed. Enter the name “Example ELISA”.
Method identification information	**.2)**	The **Method information** dialog box (see Reference Guide Section - 10.2.1 on page - 86) is displayed, enter the Manufacturer: Example Company Parameter: Hepatitis B Antigen Barcode Mask: HB#######????**** Plate Hold Time: 30 mins Pipetting Delay: 5 mins Read Access: 2 Write Access: 6
	.3)	Confirm the Method Information dialog box definition by selecting the OK push button.
Layout editor	**.4)**	The Layout editor allows the ML F.A.M.E. operator to define what goes where in the plate.
Plate configuration	**.5)**	From the **Configuration** menu select the **Set Plate Dimensions** menu choice.
	.6)	Enter the plate’s dimensions in the appropriate entry fields.
Arranging sample well types	**.7)**	First select the filling direction from the **Configuration** menu, either vertical (**A - H**) or horizontal (**1 - 12**). A marker on the menu shows which direction is selected. For this example select A - H.
	.8)	Next select the required **Replica Number** from the **Samples** menu to define the number of replicas of each sample (a value of 1 gives 1 well per sample. A value of 2 gives 2 wells per sample, etc.). In this case a value of 1 is required.

NOTE
The Barcode Mask (see Reference Guide Section - 10.2.1 on page - 86) must be unique and must correspond exactly to the barcodes used on the plates. For further information on Plate hold time and Pipetting delay see Reference Guide Section - 10.2.1 on page - 86.

ATTENTION
The plate dimensions specified in the plate configuration must correspond to dimensions of the plate, otherwise contamination, spillage or errors may occur during wash and dispense steps.

Table 3.1.1.1 - Method Definition Process (CONTINUED)

To...	Do This...
Defining control well types	**.9)** For this example the required well types are Positive Control (PC), Negative Control (NC), Samples (SA) and Blank (BL). Except for Blank well types, all the above are ML F.A.M.E. software defaults.
	.10) From the **Edit** menu select the **Edit Well Types** menu choice. Select the Insert push button. A new line is created in the table. Enter BL in the abbreviation entry field, Blank in the Used as entry field and an optional comment. Confirm the definition with the OK push button.
Deleting well types	**.11)** Delete any well types that will not be required for the test. From the **Edit** menu select the **Edit Well Types** menu choice. Select the well types to be deleted and select the Delete push button.
Assigning control well types	**.12)** Choose a well type from the Select Well Type drop-down list.
	.13) The cursor icon will change from an arrow to a Pencil (✎) indicating well edit mode, then select a well to allocate its selected well type as per the desired layout.
Completing the layout	**.14)** Select the **Arrange Samples** menu choice from the **Samples** menu to automatically complete the plate layout, assigning all remaining empty wells as sample wells. This is always the last action in laying out a plate.
Checking the layout	**.15)** Finally select the **Check Layout** menu choice from the **File** menu to automatically check the plate layout for errors.
Test processing editor	**.16)** Activate the Test Processing Editor by double clicking on its icon.
Prepare plate	**.17)** This is carried out external to the ML F.A.M.E. and the ML F.A.M.E. operator only needs to define the approximate time required to fill the plate with samples (in this example 10 minutes).

NOTE
If there are any unused well types in the layout, they must be deleted.
Remember to rearrange the layout again if well types have been deleted.

Table 3.1.1.1 - Method Definition Process (CONTINUED)

To...	Do This...
SRAM	**.18)** From the **Steps** menu select the **Sample and Reagent Addition Monitoring** menu choice.
	.19) In the displayed dialog box select a Measuring Filter of 450 nm, an optional Reference Measurement Filter and range check criteria.
Incubate	**.20)** From the **Steps** menu select the **Incubate** menu choice.
	.21) In the displayed dialog box select the Temperature controlled incubation radio button.
	.22) Enter a temperature of 37°C (default setting).
	.23) An operating temperature tolerance must be set defining the maximum variation in temperature (between 1°C and 5°C).
	.24) Select the **Fast** option from the **Heating up** drop-down list.
	.25) Enter the required incubation and tolerance times (in this example 30 minutes and 5 minutes).
Wash	**.26)** From the **Steps** menu select the **Wash** menu choice.
	.27) Select the **Plate wash** option.
	.28) Before the wash step can be used a wash solution must be defined.
Define global fluid	**.29)** From the Test Processing Editor - Wash dialog box select the Edit Global push button, then in the displayed dialog box select the New push button. The Edit Global Fluid dialog box is displayed.
	.30) Enter the Wash Fluid name - **OCD-01** - and a preparation time of 10 mins.
	.31) Confirm this with the OK push button and the new fluid will appear in the display of the Edit Global Fluids dialog box.

NOTE
Sample and **R**eagent **A**ddition **M**onitoring is used to check dispensing and can be used at any time in a test run (for further information on the SRAM step and additional functions see Reference Guide Section - 10.2.3.3 on page - 95).

NOTE
For incubation times of 30 minutes and less, fast heating up is recommended.

NOTE
Global Fluids are designated by a preceding asterisk (*) in their name.

Table 3.1.1.1 - Method Definition Process (CONTINUED)

To...	Do This...
	.32) Return to the Test Processing Editor - Wash dialog box by selecting the Close push button.
	.33) Select the new wash solution from the drop down list. Enter the required wash/dispense volume or select it from the drop-down list (In this example 370 µl) then the Number of Cycles (5 in this example), Soak Time (20 sec.) and Aspiration Height (0.3 mm).
	.34) To enter this step in the test process definition select the OK push button.
Dispense	**.35)** From the **Steps** menu select the **Dispense** menu choice.
	.36) Before the Dispense step can be used a reagent must be defined.
	.37) The reagent is specific to this method (i.e. not global), select the Edit **Method specific push button**. The Edit Method Specific Fluids dialog box is displayed.
Define method specific fluid	**.38)** Select the **New push button**. The Edit Method Specific Fluid dialog box will appear. Enter the name "**SUBSTRATE**" in the **Name** entry field then the time it will take to prepare the substrate solution.
	.39) In this case the solution is unstable so select the **Reagent Is Unstable** check box and enter the stability time (in this case 60 minutes).
	.40) Confirm this with the OK push button and the new fluid will appear in the display of the Edit Method Specific Fluid dialog box.
	.41) Select the **Close push button** and the ML F.A.M.E. software returns to the Dispense dialog box.

NOTE
In this example, no wash options are selected. To select a wash option, select the **Wash Options...** push button, additional wash options include **Continuous wash**, **Bottom wash**, **Bottom sweep** and **Pump power** (see Reference Guide Section - 10.2.3.3 on page - 95).

NOTE
For method specific reagents, it is recommended to include the method name as part of the reagent name to make barcode assignment easier during a run.

Table 3.1.1.1 - Method Definition Process (CONTINUED)

To...	Do This...
	.42) Select "**SUBSTRATE**" from the **Reagent name** drop-down list and a dispense volume of 200 µl from the **Volume** drop-down list. Select a Slow aspirate speed from the drop-down list. Select a Slow dispense speed from the drop-down list.
	.43) To enter this step in the test process definition select the OK push button.
SRAM	**.44)** See - Step 3, Item Number 18)
Incubate	**.45)** From the **Steps** menu select the **Incubate** menu choice.
	.46) In the displayed dialog box select the **Ambient** incubation radio button.
	.47) Enter the lower and upper temperature limits for ambient incubation given in the package insert (in this case 15 and 30°C).
	.48) Enter the required Incubation and tolerance times (in this example 30 minutes and 2 minutes) and select **the OK push button**.
Re-identify	**.49)** Select the **Re-identify menu choice** from the **Steps** menu to check that the plate barcode matches the one read at the start of the run.
Dispense	**.50)** From the **Steps** menu select the **Dispense** menu choice.
	.51) Before the dispense step can be used a reagent must be defined. This is a global reagent since it is not specific to any one method.
	.52) Select **Edit Global...**. The **Edit Global Fluid** dialog box is displayed.
	.53) Select the **New push button**. The **Edit Global Fluid** dialog box will appear.

Table 3.1.1.1 - Method Definition Process (CONTINUED)

To...	Do This...
	.54) Enter the name "**2 MOL/L H2SO4**" in the **Name** entry field then the time it will take to prepare (10 mins), select the **OK** push button to confirm selection. Then select the **Close** push button to return to the **Dispense** dialog box.
	.55) Select "**2 MOL/L H2SO4**" from the **Reagent name** drop-down list and a dispense volume of 50 µl from the **Volume** drop-down list.
	.56) Select the **Well** push button to define into which well types to dispense. The **Select Wells** dialog box will appear.
	.57) Choose the well types to dispense by selecting them from the **Well Types** drop down list (in this example all well types should be selected). The selected wells will appear highlighted in the plate layout.
	.58) Select **OK**. The message "All types " should appear in the **Wells** field of the **Dispense** dialog box.
	.59) Select a slow aspiration speed from the drop-down list. Select a slow dispense speed from the drop-down list.
	.60) To enter this step in the test processing definition select the **OK** push button.
Mix	**.61)** From the **Steps** menu select the **Mix** menu choice.
	.62) Select the medium mix intensity.
	.63) Select a mix time of 10 seconds, then click on the **OK** push button.
Read	**.64)** Select the **Read menu choice** from the **Steps** menu.
	.65) Select the 492 nm measuring filter from the drop-down list.

NOTE
When specifying a Photometer Filter for an assay it is important to check that this Photometer Filter is installed.

Table 3.1.1.1 - Method Definition Process (CONTINUED)

To...	Do This...
	.66) The method also requires a reference measurement. Select the **Reference measurement** check box and select the 620 nm reference filter. Then select the **OK** push button.
Check method	**.67)** Once the processing definition is completed the method must be checked for errors in the test processing definition.
	.68) Select **Check Layout And Processing Definition...** from the **File** menu to check the layout and test processing definition.
	.69) If errors were found in the layout or processing definition the ML F.A.M.E. operator will be prompted as to the type of error and its location.
	.70) Once these errors have been corrected re-check the method until no errors are returned.
Defining the first processing step	**.71)** From the **Edit** menu select the **Select First Processing Step** menu choice. A dialog box will be displayed allowing the ML F.A.M.E. operator to select the step number that will be addressed first in the run process which defines the end of the plate hold time.
Save method	**.72)** From the **File** menu select the **Save** menu choice and the method is saved in the data base under the name entered in the beginning of the definition in this case Example ELISA.

NOTE
A method that returns warnings when checked may still be run while a method returning errors will prevent the method being run.

This completes the test processing (method) definition.

3.1.2 Documenting a Test Run

Information generated by a test run can be handled in a number of ways. These are called documentation jobs. Documentation jobs are method specific and can be defined in various ways including or excluding different information. These are called documentation formats and are global, i.e. they can be used by multiple methods by being included in the method specific documentation job.

Table 3.1.2.1 - Documentation Jobs

To...	Do This...
Working with documentation formats	**.1)** From the **Methods** menu select the **Edit Globals** menu choice then the **Formats** sub-menu choice.
	.2) The **Documentation Formats** dialog box is displayed allowing the ML F.A.M.E. operator to create new documentation formats and change or delete existing ones.
Create a new or change an existing documentation format	**.3)** The **Documentation Formats** dialog box allows the ML F.A.M.E. operator to enter a name and comment for the documentation format then specify the various information to be contained in the documentation job, including trace information, OD values and plate information.
Assigning a documentation format to a doc. job and then a method	**.4)** From the **Methods** menu select the **Edit** menu choice then the **Documentation** sub-menu choice.
	.5) A dialog box is displayed listing all documentation jobs available for use. This includes the documentation format used and the destination device of that information.
New	**.6)** Select the **New** push button and in the dialog box, a list of documentation formats and possible device destinations is displayed.
	.7) Select the desired options and the Save push button and the new documentation job is displayed in the **Documentation Job** dialog box.

Table 3.1.2.1 - Documentation Jobs (CONTINUED)

To...	Do This...
Change	**.8)** The **Change** push button allows the ML F.A.M.E. operator to edit an existing Documentation Job's properties (see New above).
Delete	**.9)** To delete an existing Documentation Job select it then select the **Delete** push button.
Start documentation by user	**.10)** With this option selected the test's information must be released manually by the ML F.A.M.E. operator as opposed to automatically at the end of the run (see Reference Guide Section - 12.2.1 on page - 133).

3.1.3 Method Management

In general, it is only possible for ML F.A.M.E. operators to use the "Save As, Copy, Rename, Delete, Backup & Restore Methods" functions. The following table explains these procedures.

As most of the dialog boxes for these procedures are identical the process will be explained once in entirety then again for each further command using reference to the common elements.

Table 3.1.3.1 - Save As, Copy, Rename, Delete, Backup, Restore and Print a Method.

To...	Do This...
Save as...	**.1)** From the **Methods** menu in the main ML F.A.M.E. window select the **Manage** sub-menu then the **Save as...** menu choice.
	.2) A dialog box is displayed allowing the ML F.A.M.E. operator to enter a new name for the method.
Copy...	**.3)** If a method is open for editing the ML F.A.M.E. operator is prompted for the new method name. However, when no method is open, a dialog box is displayed listing all methods available to the ML F.A.M.E. operator on the ML F.A.M.E. database allowing the selection of the method to be copied and an entry field for its new name.

NOTE
When a copy is made of a method the new method will not have a barcode mask as no two methods can use the same barcode mask. It is then necessary to open the method, define the new barcode mask then check the full method definition. For information on barcode mask see Reference Guide Section - 10.2.1 on page - 86.

NOTE
An open method's name will not appear in the selection dialog box when Copy, Rename or Delete are selected. A method cannot be deleted if test results for that method exist on the system.

Table 3.1.3.1 - Save As, Copy, Rename, Delete, Backup, Restore and Print a Method. *(CONTINUED)*

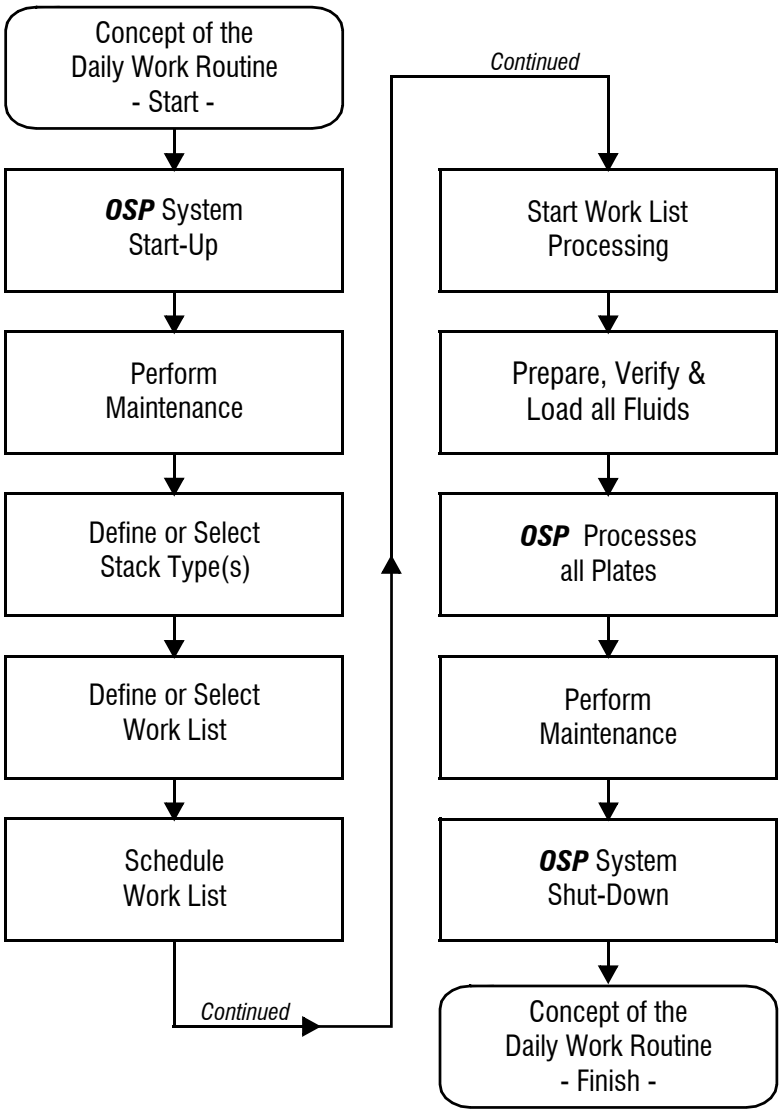
To...		Do This...
	Rename...	**.4)** Select the method from the list in the displayed dialog box and enter the new name.
	Delete...	**.5)** To delete a method select the method from the displayed list and use the delete push button. The method will be removed from the ML F.A.M.E. database.
	Backup...	**.6)** To backup an open method the ML F.A.M.E. operator must only enter a path to the desired directory, however if no method is open the ML F.A.M.E. operator is asked to first select a method.
	Restore...	**.7)** To restore a backed-up method the ML F.A.M.E. operator will be prompted for the backup path. A list of all methods that have been backed-up will then be displayed for selection.
	Print...	**.8)** With a method open for editing the print command prints that method, however with no method open the ML F.A.M.E. operator is prompted to select the method to be printed from a dialog box listing all methods available to that ML F.A.M.E. operator.

NOTE
The default back-up path for a method is defined in the Software Presettings dialog box (see Reference Guide Section - 13.2.5 on page - 142)

Chapter 4 Daily Work Routine

4.1 Concept of the Daily Work Routine

Below is a flow chart giving the logical flow of the daily work routine for the ML F.A.M.E.. Each of these steps are explained in greater detail in the following pages.


Concept of the Daily Work Routine - Start -
OSP System Start-Up
Perform Maintenance
Define or Select Stack Type(s)
Define or Select Work List
Schedule Work List
Continued
Continued
Start Work List Processing
Prepare, Verify & Load all Fluids
OSP Processes all Plates
Perform Maintenance
OSP System Shut-Down
Concept of the Daily Work Routine - Finish -

4.1.1 System Start-Up and Shut-Down

This section details the start-up procedure and outlines the tasks necessary before a test run can be started.

Table 4.2 - Starting-up and Shutting-down the ML F.A.M.E.

To...	Do This...
Start up the ML F.A.M.E.	**.1)** Turn on ML F.A.M.E. workstation power supply.
	.2) Turn on ML F.A.M.E. instrument power supply.
	.3) Enter ML F.A.M.E. operator name.
	.4) Enter password.
	.5) The instrument is then initialized to check whether the instrument and ML F.A.M.E. software are in an operable condition.
	.6) The ML F.A.M.E. software will then run a maintenance status check to establish the maintenance routines required.
	.7) The ML F.A.M.E. operator will be prompted to run cold start maintenance if: **a)** The instrument has been initialized for the first time that day. **b)** more than 24 hours have passed since the last cold start maintenance was run.
	.8) A check is made to ascertain when the ML F.A.M.E. had its last verification check. See chapter 7 for further information on verification.
Shut down the ML F.A.M.E.	**.9)** Exit all windows and editors.
	.10) From the **File** Menu in the main ML F.A.M.E. window select the **Exit** menu choice.
	.11) The ML F.A.M.E. software will then run a maintenance status check to establish the maintenance routines required.

ATTENTION
Do not switch off instrument, open drawers or transparent cover, touch load button or any moving parts during initialization.

ATTENTION
No other programs or applications should be started while the ML F.A.M.E. software is running.

ATTENTION
It is very **important** that the ML F.A.M.E. operator waits until prompted by the ML F.A.M.E. workstation before turning off the power supply. This is due to the closing of the ML F.A.M.E. database and misuse can result in ML F.A.M.E. database corruption.

4.2.1 Stack Types

Below is a step-by-step guide to working with stack types. For a general description of and further technical information on stack types, see Reference Guide Section - 11.1.1 on page - 106.

Table 4.1.2.1 - Define a New Stack Type

To...	Do This...
Define a new stack type	**.1)** From the Main ML F.A.M.E. window select the **Work** menu then the **Stack Type** menu choice then the **New** sub-menu choice.
Name the stack type	**.2)** The **New Stack Type** dialog box is then displayed, enter the desired (unique) name for the new stack type (i.e. Example Stack Type).
Add methods to the stack type	**.3)** From the **Method** list box select the method to be added to the stack type (i.e. Example ELISA), then click the **Add** push button. The selected method will be placed in the **Stack Type** list box. Continue this process until the desired stack type is achieved.
Remove methods from the stack type	**.4)** To remove a method from the stack type, select the method name in the **Stack Type** list box and click on the **Remove** push button.
Save and exit	**.5)** When all required methods are in the stack type contents list box click the **Save**/**Next** push button and then either exit the dialog box using the **Cancel** push button or repeat the above process to define another stack type.

NOTE

The List of Stack types... push button displays a list of all existing stack types.

The order in which methods are placed in a stack type does not define the order in which plates are processed in a run. The scheduler decides the optimum processing order.

Table 4.1.2.2 - Edit a Stack Type

To...	Do This...
Edit a stack type	**.1)** From the **Main** ML F.A.M.E. window select the **Work** menu then the **Stack Type** menu choice then the **Edit** sub-menu choice.
	.2) The **Stack Type Select** dialog box is then displayed, select the desired stack type from the list box.
	.3) Follow the procedures in the above table to edit and save the stack type.

Table 4.1.2.3 - Print or Delete a Stack Type

To...	Do This...
Print or delete a stack type	**.1)** From the **Main** ML F.A.M.E. window select the **Work** menu then the **Stack Type** menu choice then the **Delete** or **Print** sub-menu choice.
	.2) The **Stack Type Delete** or **Print** dialog box is then displayed, select the desired stack type from the list box.
	.3) Click the **Delete** or **Print** push button and the selected stack type is erased from the ML F.A.M.E. database or printed to the OS/2 default printer.

4.1.3 Kit Lot Editor

The **Kit Lot Editor** is only available if the **Kit Lot Documentation** option was selected during the installation procedure. When using the **Kit Lot Editor** the defined kit lot will be documented and any kit lot information provided in the plate barcode or in the barcode file will be ignored.

If this installation option is not selected then the ML F.A.M.E. software will perform an active kit lot check and compare the loaded kit lot elements with the defined elements.

Table 4.1.3.1 - Working with the Kit Lot Editor

To...	Do This...
Define a new kit lot	**.1)** From the **Main** ML F.A.M.E. window select the **Work** menu then the **Kit Lot Editor** menu choice.

Table 4.1.3.1 - Working with the Kit Lot Editor

To...	Do This...
	.2) The **Kit Lot Editor** is displayed and lists all currently stored kit lot data on the system in the path defined in the software presettings.
Define a kit lot for a method	**.3)** From the **Edit** menu select the **Insert Kit Lot** menu choice.
	.4) Select a method from the pull-down list and then select the **OK** push button.
	.5) A dialog box is displayed where the new kit lot is assigned to an existing method, its expiration date and components (with the component lot numbers) can be defined.
Define the kit lot of a global fluid	**.6)** From the **Edit** menu select the **Insert Global Fluid** menu choice.
	.7) Here the ML F.A.M.E. operator may select a global fluid name, its expiration date, whether it is a single or dual component and the either a single component lot number or two lot numbers if it is a dual component.

4.1.4 Work Lists

Below is a step-by-step guide to working with work lists (for further information on work lists see Reference Guide Section - 11.1.1 on page - 106).

For the purposes of these examples it is assumed that all method data is correct and kit lots exist and are date validated.

Table 4.1.4.1 - Define a New Work List

To...	Do This...
Define a new work list	**.1)** From the **Main** ML F.A.M.E. window select the **Work** menu then the **Work List Manager** menu choice.
	.2) The **Work List Manager** window is then displayed.
Include a stack in a work list	**.3)** From the **Edit** menu select the **Insert Stack Type** menu choice.
	.4) A dialog box is displayed listing all available stack types.

NOTE
Each individual Method's state is checked to ensure it is error free and that the corresponding Kit Lot is correct for the method and the expiry date has not been reached.

NOTE
It is ***not possible*** to perform any actions on a work list (or individual stack in the list) that has a status of planned or running. In order to edit the properties of a stack the planned work list must be un-scheduled (see Table 4.1.4.3, "Scheduling and Un-scheduling a Work List," on page 47). Therefore, running work lists and their stack types cannot be edited.

NOTE
The ML F.A.M.E. software allows two way of defining the earliest starting time for a stacks processing: either time of day (i.e. the ML F.A.M.E. operator defines an actual time for the start) or as an offset to the previous stacks start time. When the first stack uses the offset time the start time is offset from the time the stack is planned.

Table 4.1.4.1 - Define a New Work List (CONTINUED)

To...	Do This...
	.5) Select the required stack type name (i.e. Example Stack Type) from the list and click on the **Insert** push button.
	.6) After a moment the stack will appear in the **Work List Manager** window. For further information on the contents of the **Work List Manager** window, see Reference Guide Section - 11.3 on page - 109.
	.7) To insert a stack in-between two stacks, select the lower of the two and use the Insert menu choice from the **Edit** menu. The new stack will be placed above the selected stack.
Remove a stack from a work list	**.8)** Select the stack to be removed from the work list and either select the **Delete** menu choice from the **Edit** menu or press the keyboard **Del** key.
	.9) Repeat this process until the desired work list arrangement is achieved. Then select the **Close** push button to return to the **Work List Manager** window.
Define the earliest start time	**.10)** Select the stack type name and then from the **Edit** menu the **Set Earliest Start Time** menu choice.
	.11) Set the Time of Day or the Delay to the Previous Stack.
Change the kit lot	**.12)** By selecting an individual method in a stack and the **Change Kit Lot** menu choice from the **Edit** menu a dialog box is displayed listing all kit lots available for use with this method (also see Table 4.1.3.1 - Working with the Kit Lot Editor)
	.13) Select the required kit lot and click the **OK** push button. All methods of the type selected will now use the new kit lot.
Print the work list	**.14)** From the **File** menu select the **Print** menu choice, the work list data will be printed on the default OS/2 printer.

Table 4.1.4.1 - Define a New Work List (CONTINUED)

To...	Do This...
Save the work list	**.15)** From the **File** menu select the **Save As** menu choice, a dialog box is displayed where the (unique) work list name is entered (i.e. Example Work List). Select the **Save** push button and the work list is stored in the ML F.A.M.E. database. There is also a **Display List** push button that allows the ML F.A.M.E. operator to view a list of all, available, defined work lists.

Table 4.1.4.2 - Edit a Work List

To...	Do This...
Edit a work list	**.1)** To edit an existing work list select the **Open** menu choice from the **File** menu, a dialog box is displayed listing all available work lists.
	.2) Select the desired work list and follow the steps in the above table to either add new stacks or delete existing ones.

Once a work list has been created it is then possible to create a schedule of processing events as follows:

Table 4.1.4.3 - Scheduling and Un-scheduling a Work List

To...	Do This...
Schedule a work list (creating a plan)	**.1)** To schedule the running of the open work list select the **Schedule** menu choice from the **Actions** menu in the **Work List Manager** window.
	.2) A progress indicator is displayed indicating the percentage of the work list scheduling completed.
	.3) When scheduling is completed the **Plan** window is displayed. For further information on the contents of the **Plan** window see Reference Guide Section - 11.4 on page - 112.

Table 4.1.4.3 - Scheduling and Un-scheduling a Work List

To...		Do This...
Work list status	**.4)**	When a work list has been successfully scheduled the stack and individual methods status will change from Not Planned to Planned. All time lines defined for the stacks are now active and no further options can be defined for this work list.
Un-schedule a planned work list.	**.5)**	Once a work list has been scheduled and the ML F.A.M.E. software has switched focus to the **Plan** window, select the **Work List** menu choice from the **View** menu (or use the **F7** key) to change the focus back to the **Work List** Manager.
	.6)	Select the required stack (see Note) and then from the **Actions** menu the **Un-schedule** menu choice.

NOTE
Un-scheduling is a sequential process, i.e. it is not possible to un-schedule an individual stack positioned in the middle of a work list, selecting an individual stack like this to un-schedule will un-schedule the selected stack and all following stacks in the work list.

4.1.5 Executing and Aborting a Run

After successfully scheduling a work list the **Plan** window is displayed (for further information on the **Plan Window** and its contents see Reference Guide Section - 11.4 on page - 112).

At this stage the ML F.A.M.E. operator should load all stable fluids, please see section section 4.1.6 "Fluids" for a step-by-step guide to working with fluids.

Table 4.1.5.1 - Starting a Run

To...	Do This...
Start a run	**.1)** From the **Actions** menu select the **Start Run** menu option.
	.2) The work list will now start processing using the ML F.A.M.E. software defined schedule.
ML F.A.M.E. *operator actions*	**.3)** The ML F.A.M.E. operator will be prompted when action is required.
	.4) Prepare plate(s): The ML F.A.M.E. operator is prompted to start the plate preparation given the time specified in the prepared plate step of the method definition.
	.5) Load stack: The ML F.A.M.E. operator is prompted to load the appropriate stack then press the instrument's **Load** button.
Edit plate barcode information	**.6)** When a plate is loaded a search is made to find the plate's barcode data. If this search can not find any information the **Pipetting Information Error** dialog box is displayed. By selecting **Retry** or **Search In Path** another search is made to find the pipetting information. With in this dialog box it is then possible to select the **Edit Plate** push button displaying the **Edit Plate** dialog box.
	.7) Here it is possible to include or exclude samples and to edit a wells barcode
	.8) Load Unstable Fluid(s): Table 4.1.6.2, "Assigning Fluids in the Plan Window," on page 52.

NOTE
This option is only available if the Plate Access On installation option was selected.

ATTENTION
Selecting Retry or Search in path must be carried out within two minutes.
If any samples must be excluded or included this must be done prior to the first aspirate, wash or SRAM step. If there is insufficient time for this, it is possible to add an ambient incubation step.
Well barcodes can be entered until before the start of documentation.

Table 4.1.5.1 - Starting a Run (CONTINUED)

To...	Do This...
Abort a test/run	**.9)** To abort an individual test or an entire run the ML F.A.M.E. operator must switch to the **Work List** Manager, use the **Work List** menu choice from the **View** menu or the **F7** keyboard key.
	.10) To abort an individual test select the test and from the **Abort** menu use the **Selected Test** menu choice, confirm the action and the test is removed from the schedule.
	.11) The entire run can be aborted at any time by following the above procedure but selecting the **Entire Run** menu choice.

NOTE
Individual test can only be aborted when the plate has actually been loaded onto the instrument.
Aborted tests will appear grey in the Plan window.
All aborted plates will be transported to the exit module.

4.1.6 Fluids

ATTENTION
It is important that the ML F.A.M.E. operator ensures that the correct fluids are placed in the correct, labeled, container.

NOTE
Please consult with the manufacturer of stable fluids to ascertain the exact stability status of their fluids.

NOTE
It is important that the ML F.A.M.E. operator check each barcode while placing it on any ML F.A.M.E. part to ensure it is in a serviceable condition.

NOTE
To avoid possible errors during a run due to incorrect loading of fluids, please label all fluid containers and storage containers.

Fluid Loading

It is highly recommended that stable fluids which have a close loading time, i.e. are the first fluids to be loaded, be loaded together and assigned with a location and barcode prior to starting a run. This will reduce the amount of time-critical work for the ML F.A.M.E. operator during the run and will limit possible problems caused by delays. The procedure for this is explained below in the Assignment Editor section (Table 4.1.6.1, “Assignment Editor,” on page 51).

While stable fluids are loaded before starting the run, unstable fluids must be loaded when the ML F.A.M.E. software requests them.

While unneeded fluids may be removed from the ML F.A.M.E. when prompted by the ML F.A.M.E. software, this may not be done if a dispensing step is scheduled for the next 5 minutes.

For further information on fluids see Reference Guide Section - 11.5 on page - 116.

Fluid Assignment

Two procedures are possible for assigning fluids:

- **The Assignment Editor (Stable Fluids)** - allows the independent assignment of fluids and their barcodes. Not available while the **Work List Manager** is active.

Table 4.1.6.1 - Assignment Editor

To...	Do This...
Insert a fluid	**.1)** Open the **Assignment Editor** using the **Assignment Editor** menu choice from the **Work** menu in the main ML F.A.M.E. window.
	.2) From the **Edit** menu select the **Insert Fluid** push button (or use the **Insert** key on the keyboard) the **Insert Fluid** dialog box is displayed.
	.3) Two selection fields are displayed: **a)** **Method** - lists all methods currently available on the ML F.A.M.E. database. **b)** **Fluid** - lists all fluids available for the selected method. The * in the method list indicates global fluids.
Select global fluids	**.4)** To assign a global fluid select the * in the **Methods** list box. Then from the list of fluids displayed in the **Fluids** list box select the desired fluid name then the **OK** push button.
Select method-specific Fluids	**.5)** Select the method from the **Method** list, any method specific fluids will be displayed in the **Fluid** list. Select the desired fluid and click the **OK** push button.
Assign the fluid	**.6)** After the above steps the **Assign** dialog box is displayed. Here the ML F.A.M.E. operator must select the module where the fluid is stored and dispensed from. The container barcode information is entered in the **Assign Container Barcode** entry field.
	.7) Select the **Add** push button. The fluid is now assigned and ready for loading.
Exiting the assignment editor	**.8)** When all desired fluids have been assigned select the **Close** menu choice from the **File** menu. The fluid will be displayed in the **Assignment Editor** window with the specified information.

❒ **After Scheduling (Unstable Fluids)** - After a successful work list scheduling the data defined in the **Assignment Editor** can be overruled in the **Plan** window.

For further information on the contents of the **Plan Window** see Reference Guide Section - 11.4 on page - 112.

Table 4.1.6.2 - Assigning Fluids in the Plan Window

To...	Do This...
Select a fluid	**.1)** Select the desired fluid in the **Fluid** column of the **Plan** window.
	.2) From the **Actions** menu select the **Assign Fluids** menu choice or use the F4 keyboard key.
Barcode entry	**.3)** The **Assign Fluids** dialog box is displayed. Then enter the container barcode.
Fluid verification	**.4)** When the component lot number has been entered (either using the barcode scanner or manually using double blind entry) and is correct, select the **OK** push button. The fluid is now assigned and ready for loading.

NOTE
When the Load Fluid Container dialog box is displayed, the first column of which will indicate whether the fluid has been verified. A marker, i.e. >, beside the fluid entry means the fluid is verified.

The normal procedure for fluid barcode assignment is by manual entry of the barcode.

4.1.7 Barcode Scanner or Double-Blind Entry

Under certain circumstances the ML F.A.M.E. operator must use the hand- held barcode scanner or double-blind entry procedure.

These circumstances include:

❒ Plate barcode not readable

❒ To verify a component lot number

❒ Correlate wash fluid

Table 4.1.7.1 - Double-Blind Entry

To...	Do This...
Manually enter barcode information	**.1)** When required by the ML F.A.M.E. software or selected by the ML F.A.M.E. operator a dialog box is displayed where barcode correlation is required.

Table 4.1.7.1 - Double-Blind Entry

To...	Do This...
	.2) The ML F.A.M.E. operator must enter the required barcode in the entry field via the keyboard.
	.3) When entered press the **Tab** keyboard key. The entered barcode will disappear.
	.4) Enter the barcode again and press the Tab key, the ML F.A.M.E. software will check that the two entered barcodes are identical. If so, the barcode correlation is complete.

Chapter 5 Test Results & ML F.A.M.E. Traces

Table of Contents

5.1 - Test Results - Overview 56
5.1.1 - The Test Results Window 56
5.1.2 - The Test Result Report Dialog Box....58
5.2 - ML F.A.M.E. Traces - Overview 59
5.2.1 - The Trace Window....60

5.1 Test Results - Overview

Once a test has been processed by the system, all resulting data can be accessed from the **Test Results** Window.

5.1.1 The Test Results Window

After the processing of a test, whether successfully completed or not, the results are stored on the ML F.A.M.E. database. The following tables give a step-by-step guide to working with these results.

Table 5.1.1.1 - Test Results Window - Procedures

To...	Do This...
Open the test results window	**.1)** From the **Results** menu in the **Main** ML F.A.M.E. window select the **Test Results** menu choice.
	.2) The **Test Results** window is displayed listing the available test results stored on the ML F.A.M.E. database.
Select viewing options	**.3)** From the **View** menu select the **List Tests by Run Status** menu choice.
	.4) In the displayed dialog box, two check boxes allow the ML F.A.M.E. operator to select: **a)** **Processed** - when checked will display all tests with the run status 'Processed'. **b)** **Documented** - when checked will display all tests with the run status 'Documented'.
Refresh the display	**.5)** To update the **Test Results** window, either select the **Refresh Now** menu choice from the **View** menu or use the **F5** keyboard key.
Delete tests	**.6)** There are three ways to delete tests from the ML F.A.M.E. database. Each is explained in the following section.
Delete a Single Test	**.7)** To delete an individual test from the ML F.A.M.E. database, select the desired test, then from the **Tests** menu select the **Delete Selected Test(s)** menu choice.
	.8) Confirm this action and the test will be erased.

NOTE
A user needs the necessary access rights to delete data. Ensure that any tests to be deleted have been documented. Tests deleted from the ML F.A.M.E. database cannot be recovered.

Table 5.1.1.1 - Test Results Window - Procedures (CONTINUED)

To...	Do This...
Deleting multiple tests	**.9)** To delete multiple tests it is first necessary to enable multiple test selection.
Enable multiple test Selection	**.10)** Select the **Enable Multiple Test Selection** menu choice from the **Tests** menu.
	.11) It is now possible to select more than one test at a time. To deselect a selected test just click on the test.
	.12) Select the desired tests to be deleted then the **Delete Selected Test(s)** menu choice.
	.13) Confirm this action and the selected tests will be erased.
Delete tests by criteria	**.14)** From the **Tests** menu select the **Delete Test by Criteria** menu choice.
	.15) Three radio button options are available in the displayed dialog box. **a)** **All Existing Tests** - this will delete all test result data from the ML F.A.M.E. database. **b)** **Documented Tests Only** - this will delete all tests whose documentation has been released. **c)** **Aborted Tests Only** - this will delete all tests whose error status is marked as aborted (see Reference Guide Section - 12.1.1 on page - 131).
Batch documentation	**.16)** With the multiple test selection option active, select the tests to be documented.
	.17) From the **Tests** menu select the **Documentation Tests Batch** menu choice.
	.18) A dialog box will display the currently available documentation format options (See Cook Book page - 37) and destination devices.
	.19) Select the desired options and then the **Document** push button. All defined criteria will be followed for the selected tests.

5.1.2 The Test Result Report Dialog Box

Table 5.1.2.1 - Test Result Reports

To...	Do This...
View a test result's report	**.1)** From the displayed list select the required test's results line.
	.2) Then from the **Tests** menu select the **Show Test Results Report** menu choice or double click with the pointer placed over the required line.
	.3) The **Test Results Report** dialog box is displayed giving detailed information about the selected test (see Reference Guide Section - 12.1 on page - 130).
View an individual well's details	**.4)** Select the desired well from the graphical display then select the **Well Details** push button. The **Well Details** dialog box gives full well details.
Exclude a well	**.5)** From the **Well Details** dialog box select the **Exclude Well** push button.
Attach a message to a well	**.6)** From the **Well Details** dialog box select the **Insert Well Comment** push button.
	.7) A dialog box is displayed where the ML F.A.M.E. operator can attach a short message to the selected well.
View well data in a tabulated format	**.8)** Select the **Table View** push button in the **Test Results Report** dialog box.
	.9) The **Test Results Report - Table View** dialog box is displayed.
	.10) The **Sort** push button allows the user to specify the listing order of the data.
View the test trace	**.11)** Select the **Test Trace** push button to view any information attached to the results of the selected test.
	.12) A comment may also be attached by the ML F.A.M.E. operator.
Manually release the documentation for the test	**.13)** Select the **Document** push button in the **Test Results Report** dialog box.
	.14) All defined documentation criteria for the selected test will be followed (see Reference Guide Section - 10.2.4.1 on page - 101).

NOTE
Once a well has been excluded it is not possible to re-include the well. The ML F.A.M.E. operator who excluded the well and the time and date of exclusion are noted in the trace file.

NOTE
It is only possible to document tests with the status Processed or documented.

Table 5.1.2.1 - Test Result Reports (CONTINUED)

To...	Do This...
Print the test result reports for the selected test	**.15)** Select the **Print** push button in the **Test Results Report** dialog box.
	.16) The ML F.A.M.E. software will now print, on the OS/2 default printer, the information as defined in the documentation format (see Reference Guide Section - 3.1.2 on page - 37): a graphical representation of the test's plate containing the OD reading and the well barcode. a table containing - well ID, barcode, OD, MW, RW and the well flag.
View the well OD/barcode	**.17)** There are two radio buttons in the bottom left of the **Test Results Report** dialog box. Select the **Display barcodes** radio button to display the individual well barcodes.

5.2 ML F.A.M.E. Traces - Overview

Virtually all actions of the ML F.A.M.E. and ML F.A.M.E. software are stored in the Trace section of the ML F.A.M.E. database. Three types of tracing are recorded:

- **Well Trace** - tracks only exceptional events for the wells in a test and is normally blank.
- **Test Trace** - tracks all events and data for each and every test.
- **System Trace** - tracks all important events and data throughout the entire system and includes ML F.A.M.E. operator actions, ML F.A.M.E. software functions, ML F.A.M.E. procedures and also important test trace information.

5.2.1 The Trace Window

The following section gives a step-by-step guide to working with these traces.

Table 5.2.1.1 - The Trace Window

To...	Do This...
Open the Trace window	**.1)** From the **Services** menu in the **Main** ML F.A.M.E. window select the Trace menu choice.
	.2) The **Trace** window is displayed listing the available trace information stored on the ML F.A.M.E. database as per the defined view criteria.
Print the trace information	**.3)** From the **File** menu select the **Print** menu choice. The displayed information is printed on the default OS/2 printer.
Store the trace information	**.4)** From the **File** menu select the **Save As** menu choice.
	.5) A dialog box will then ask the ML F.A.M.E. operator to enter a file name. The trace information is recorded in this file.
Attaching messages	**.6)** The ML F.A.M.E. operator can insert messages to any of the three types of traces.
Well messages	**.7)** From the **Edit** menu select the **Insert Well Comment** menu choice. A dialog box is displayed where the ML F.A.M.E. operator must select the test containing the required well.
	.8) Once a test has been selected the ML F.A.M.E. operator must then select a well from the graphical display, then the **Insert Well Comment** push button.
	.9) A dialog box is displayed allowing the entry of up to 80 characters.
	.10) Select the **Save** push button to confirm the message.
Test messages	**.11)** The procedure for inserting a test trace is the same as the well trace but without step 8 above.

Table 5.2.1.1 - The Trace Window (CONTINUED)

To...	Do This...
System messages	**.12)** To insert a system trace select the **Insert System Comment** menu choice from the **Edit** menu.
	.13) A dialog box is displayed allowing the entry of up to 80 characters.
	.14) Select the **Save** push button to confirm the message.
Deleting system Traces	**.15)** From the **Edit** menu select the **Delete System Traces** menu choice.
	.16) A dialog box is displayed where the ML F.A.M.E. operator is asked to select a date. All system traces recorded before this date will be erased from the ML F.A.M.E. database.
Viewing a well trace	**.17)** From the **View** menu select the **Well Trace** menu choice. A dialog box is displayed where the ML F.A.M.E. operator must select the Test containing the required well.
	.18) Once a test has been selected the ML F.A.M.E. operator must then select a well from the graphical display, then the **View Well Trace** push button.
	.19) The trace information for the specified well is then displayed.
Viewing a test trace	**.20)** From the **View** menu select the **Test Trace** menu choice. A dialog box is displayed where the ML F.A.M.E. operator must select the required test.
	.21) The trace information for the specified test is then displayed.
View the system trace	**.22)** From the **View** menu select the **System Trace** menu choice.
	.23) A dialog box is displayed allowing the ML F.A.M.E. operator to select the date for which systems trace information are to be displayed.
	.24) The system trace is then displayed.
Set the trace display priority	**.25)** From the **View** menu select the **Set Priority** menu choice.

NOTE
The ML F.A.M.E. database will store a maximum of 14 individual days of system traces.

Table 5.2.1.1 - The Trace Window (CONTINUED)

To...	Do This...
	.26) Three options are allowed: **1)** **Note** - displays all messages **2)** **Warning** - displays all messages except Notes **3)** **Error** - displays all messages except Notes and Warnings
Refresh the display	**.27)** From the **View** menu select the **Refresh** menu choice or use the **F5** keyboard key.

Chapter 6 Instrument Status

Table of Contents

6.1 - Instrument Status Window.....64
6.1.1 - Unlocking Instrument Functions 64

6.1 Instrument Status Window

The **Instrument Status** window allows the ML F.A.M.E. operator to view the incubator temperature status of each incubator slot and also lock and/or unlock instrument functions.

6.1.1 Unlocking Instrument Functions

Table 6.1.1.1 - Change Lock Status

To...	Do This...
Access required functions	**.1)** In the **Main** ML F.A.M.E. window select the **Instrument Status** menu choice from the **Services** menu.
	.2) The **Instrument Status** window is displayed. Initially the display will be in incubator temperature mode.
View a function's lock status	**.3)** From the **View** menu select the **Lock Status** menu choice. The display will change to show all present ML F.A.M.E. modules and their lock status.
Unlock an instrument function	**.4)** Select the module containing the locked function from the **Change Lock Status** menu.
	.5) All functions related to the selected module are displayed (see Reference Guide Section - 13.2.1 on page - 138).
	.6) Select the check box for the function to be unlocked and the **OK** push button.

NOTE
Unlocking a function can take some time and if the dialog box is reopened a Unlocking message will be displayed for functions currently being unlocked.

Chapter 7 ML F.A.M.E. Verification

Table of Contents

7.1 - Overview....66
7.1.1 - Pre-verification....66
7.1.2 - Verifying an Instrument Module....68

7.1 Overview

NOTE
A warning dialog box will be displayed giving 14 days notice of any required verification procedures.

Verification is an in-built self checking system of the functionality of the ML F.A.M.E.. All physical modules of the instrument are tested against predefined values using a verification kit with tested, known values.

These checks must be performed at a regular interval to ensure reliable operation of the ML F.A.M.E..

This chapter explains, step-by-step, each verification procedure. For further technical information see Reference Guide Section - 14 on page - 147.

7.1.1 Pre-verification

ATTENTION
Photometer filters 620 and 405 nm must be present to perform verification.

Before the verification process can be started it is necessary to supply the ML F.A.M.E. software with validation data for the verification kit. Three criteria exist and are explained below.

Table 7.1.1.1 - Photometer Verification Validation

To...		Do This...
Validate the photometer	**.1)**	Before the photometer verification the ML F.A.M.E. software requires reference data.
	.2)	Supplied with the verification kit is a diskette containing the reference data.
	.3)	From the **Validation** menu select the **Load Photometer Reference Data** menu choice.
	.4)	Insert the supplied diskette into the specified drive and confirm with the **Yes** push button.
	.5)	The predefined reference data is loaded into the ML F.A.M.E. database and the Photometer may now be verified.

Table 7.1.1.2 - Dispenser Verification Validation

To...		Do This...
Validate the dispenser	**.1)**	To validate the dispenser it is first necessary to establish three known values for a hand pipette, as a reference, then supply this information to the ML F.A.M.E. software.
	.2)	From the **Validation** menu select the **Dispenser** menu choice.

Table 7.1.1.2 - Dispenser Verification Validation (Continued)

To...	Do This...
	.3) In the displayed dialog box enter the required data and select the **Save** push button.
	.4) Only after this data is supplied is it possible to verify the dispenser module.

Table 7.1.1.3 - Washer Verification Validation

To...	Do This...
Validate the washer	**.1)** For the purposes of traceability it is required that the serial number(s) of the washer manifold(s) be recorded.
	.2) From the **Validation** menu select the **Washer** menu choice.
	.3) In the displayed dialog box enter the required data (see Reference Guide Section - 14.4.1 on page - 166) and select the **Save** push button.
	.4) Only after this data is supplied is it possible to verify the washer module.

Table 7.1.1.4 - Incubator Verification Validation

To...	Do This...
Validate the incubator	**.1)** The incubator check plate must be registered with the ML F.A.M.E. software to establish temperature offset and a validity date.
	.2) From the **Validation** menu select the **Incubator** menu choice.
	.3) In the displayed dialog box enter the incubator check plate serial number, the predefined temperature tolerance and its validity date, then select the **Save** push button.

7.1.2 Verifying an Instrument Module

The ML F.A.M.E. operator will be prompted when verification is required. The instrument verification procedure is a predefined process with step-by-step instructions displayed on screen at the appropriate times. However, to access these procedures at other times use the following:

Table 7.1.2.1 - Starting Verification Manually

To...	Do This...
Access verification window	**.1)** From the **Services** menu in the main ML F.A.M.E. window select the **Verification** menu choice.
	.2) From the **Procedure** menu all verification options are listed. For further information on the **Verification** window, see Reference Guide Section - 14.4 on page - 165.

Chapter 8 ML F.A.M.E. Maintenance

Table of Contents

8.1 - Maintenance - Overview....70
8.1.1 - Maintenance Procedures....70
8.1.2 - Washer Manifold....71
8.1.3 - Manual Maintenance Procedures....74

8.1 Maintenance - Overview

While most of the procedures required to perform ML F.A.M.E. maintenance are guided by the ML F.A.M.E. software some manual actions are still required by the ML F.A.M.E. operator.

This chapter gives a step-by-step guide to the initiation of these maintenance tasks and to the aforementioned manual ML F.A.M.E. operator actions.

8.1.1 Maintenance Procedures

- ❒ Cold Start - must be run after the first ML F.A.M.E. initialization of the day or after every 24 hours of operation.
- ❒ Daily - before ML F.A.M.E. shut-down if it has not been run for one day.
- ❒ Weekly - before ML F.A.M.E. shut-down if it has not been run for one week.
- ❒ Monthly - before ML F.A.M.E. shut-down if it has not been run for one month.

NOTE
If the ML F.A.M.E. operator declines to run either, weekly or monthly maintenance before shut down, upon the next initialization these routines must be run.

Table 8.1.1.1 - Accessing the Maintenance Procedures

To...	Do This...
Start maintenance procedures	**.1)** From the **Services** menu in the **Main** ML F.A.M.E. window select the **Maintenance** menu choice.
	.2) The **Maintenance** window is displayed allowing the ML F.A.M.E. operator to view the maintenance status of each ML F.A.M.E. module (see Reference Guide Section - 15.1.3 on page - 171).
	.3) From the **Procedure** menu select the desired maintenance routine.
	.4) The ML F.A.M.E. software will then issue on screen instructions detailing all procedures required to perform the selected maintenance procedure.

For general information on running maintenance procedures see Reference Guide Section - 15.1 on page - 170.

8.1.2 Washer Manifold

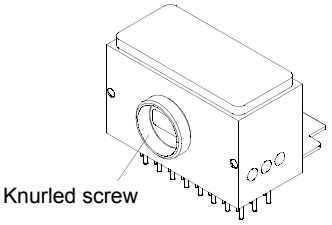
ATTENTION
Wear protective gloves when handling the washer manifold as it may be contaminated. Manifold needles could puncture protective gloves.

NOTE
Manifold removal is a part of the monthly maintenance process and is initiated independently from any menu commands.

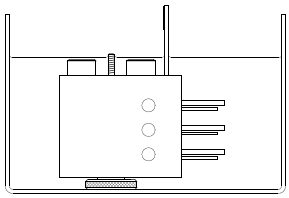
The washer manifold must be removed from the ML F.A.M.E. monthly for service or maintenance/cleaning. The following outlines this procedure.

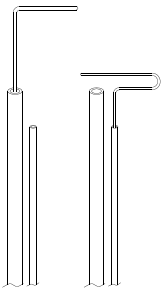
Table 8.1.2.1 - Remove, Wash and Install Washer Manifold

To...	Do This...
Remove the washer manifold	**.1)** From the **Extras** menu in the **Maintenance** window select the **Remove Manifold** menu choice then the required **Washer** sub-menu choice.
	.2) The selected manifold will then be lowered into the removal position.
	.3) Release knurled screw on the front of the manifold.
	.4) Withdraw the manifold from its guide rods.
Clean the washer manifold	**.5)** Remove the cap from the manifold.
	.6) Remove the plugs from the manifold once a month. Use the 3 mm allen screw driver to push the plugs through the manifold bores.
	.7) Soak the manifold, the cap and the plugs in a solution of *Microlab™ Detergent and Disinfectant* (please see the product data sheet for further information). *Do not immerse the connector board* (see left).
	.8) Clean the manifold bores using the brush supplied with the manifold cleaning kit and warm tap water.
	.9) Use the cleaning sticks in the mechanical kit only if needles are totally blocked. Using these sticks could damage the inner part of the needles.
	.10) If it is necessary to solute obstructions, clean the manifold in an ultrasonic bath.
	.11) After the above procedures rinse all items with deionized water.



ATTENTION
Do not use water hotter than 50°C to clean the manifold and do not dry or store at temperatures > 50°C.



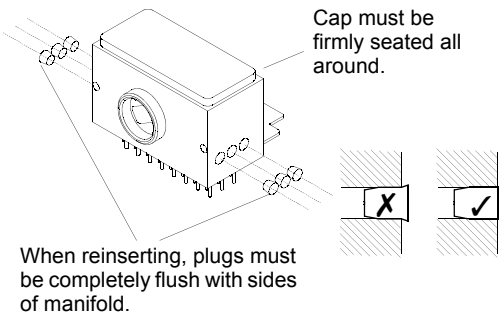


Cleaning Aspirating/Dispensing Needle

Insert cleaning stick into aspirating needle and slide in and out.

Table 8.1.2.1 - Remove, Wash and Install Washer Manifold (CONTINUED)

To...	Do This...
Ultrasonic bath method	**.12)** Clean the manifold needles by placing the manifold in an ultrasonic bath containing *Microlab™ Detergent and Disinfectant* solution for 5 minutes. Do not immerse the connector board.
	.13) After the above procedures rinse all items with pipe water and deionized water.
Washer manifold assembly	**.14)** Examine each manifold plug for scratches or any signs of damage. If signs of scratching or damage are apparent, replace with a new plug.
	.15) Reinsert the plugs into the manifold. The plugs must be completely flush with the sides of the manifold and the cap must be firmly seated all-around.
	.16) Replace the cap on the manifold.
Clean wash shell	**.17)** The wash shell is the white plastic molding which sits under the washer manifold when it is raised. It pivots down and back when the manifold is lowered.
	.18) The wash shell should <u>not</u> be removed from the instrument for cleaning. Swing it down to clean its vertical position and clean it with a cloth soaked in *Microlab™ Disinfectant Spray* (wearing protective gloves).
Reinstall washer manifold	**.19)** From the **Extras** menu in the **Maintenance** window select the **Insert Manifold** menu choice then the required **Washer** sub-menu choice. Follow the on screen instructions for the safe removal of the manifold.

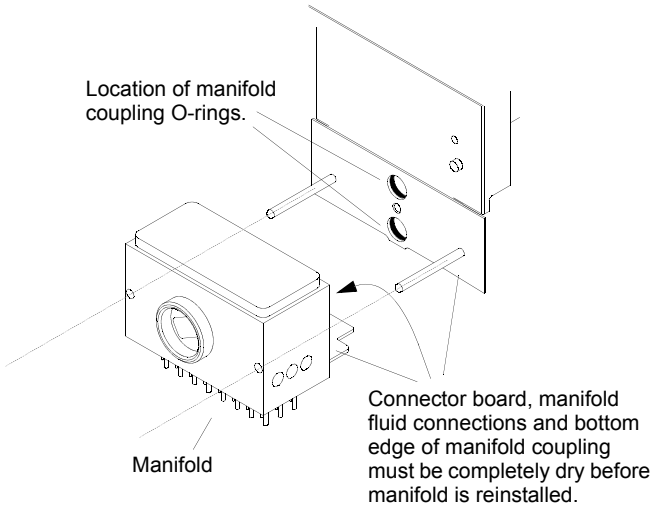


NOTE

Ensure the connector board at the back of the manifold, the needles, the fluid connections and the bottom edge of the manifold coupling are completely dry before reinstallation. Wet the manifold coupling O-rings using a paper towel soaked in deionized water.

Table 8.1.2.1 - Remove, Wash and Install Washer Manifold (CONTINUED)

To...	Do This...
	.20) Slide the manifold onto its guide rods and tighten the knurled screw until solid resistance is met (between 11 and 14 revolutions).


Location of manifold coupling O-rings.
Connector board, manifold fluid connections and bottom edge of manifold coupling must be completely dry before manifold is reinstalled.
Manifold

8.1.3 Manual Maintenance Procedures

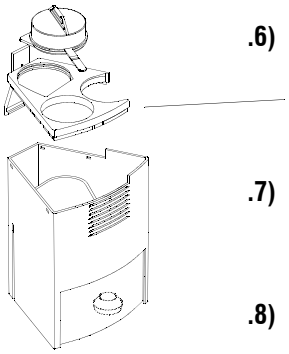
ATTENTION
Do not clean the instrument in the vicinity of naked flames or devices which could create sparks. Do not use hot air blowers to dry the instrument. Flammable liquids are used for cleaning.
Wear gloves when cleaning the instrument and removing the washer manifold.

ATTENTION
Do not use water hotter than 50°C to clean reagent containers and do not dry or store at temperatures > 50°C. Cold deionized water is recommended.
Make sure that the conductive insert is still in place after washing a reagent container.

NOTE
Research has shown that syringes can be used for a maximum period of one (1) week if an appropriate cleaning procedure is applied. The decision to reuse lies with the operator and should be made in accordance with the guidelines of Good Laboratory Practice (GLP). For more details, refer to your reagent manufacturer for an approved syringe cleaning procedure.

ATTENTION
Never pull the plunger completely out of the syringe; this damages the syringe.

Table 8.1.3.1 - Manual Cleaning - Daily Maintenance

To...	Do This...
Waste containers	**.1)** Fill the contaminated waste container with a suitable disinfectant, leave to soak, as recommended by the manufacturer.
	.2) Empty the container, rinse thoroughly with water and leave to dry.
External water separator	**.3)** Do the same for the external water separator.
Waste cap	**.4)** Clean the outside of the waste cap with a cloth soaked in *Microlab™ Disinfectant Spray*.
Reagent containers	**.5)** Remove the barcode label from the reagent container.
	**.6)** Immerse the reagent containers in deionized water. Note that the lids of the reagent containers can be removed if necessary.
	.7) Alternatively clean the reagent containers in a laboratory washing machine.
	.8) Empty and leave to dry.
Clean/dispose of syringes	**.9)** Fill the syringe manually once with deionized water.
	.10) Leave the filled syringe, free of air bubbles, to stand in an upright position overnight.
	.11) Examine the syringe for the overnight formation of air bubbles (> 1 cm). Any such air bubbles indicate a faulty syringe.
	.12) Empty the syringe before reusing.

If syringes are used for more than one run, dedicate each syringe to a specific reagent. Mark each syringe clearly with the name of the reagent for which it is intended.
Some reagents may require the use of a new syringe every day. Check with the reagent manufacturer's recommendations specific to each assay and reagent.

Table 8.1.3.2 - Manual Cleaning Weekly Maintenance

To...	Do This...
Washer manifold	**.1)** Remove and clean the washer manifold if the needles are blocked, otherwise every month.
Clean instrument housing, entry lift, entry stack and plate transport system	**.2)** Clean using *Microlab™ Disinfectant Spray* directly onto all surfaces, then wipe clean.
Transparent cover and exit stack	**.3)** Open and remove (if necessary) the transparent cover.
	.4) To remove the cover, slide the two locking pins located at each end by the hinges inwards and lift the cover out.
	.5) Spray the cover with *Microlab™ Disinfectant Spray* and wipe it dry.
	.6) Clean the exit stack in the same way.
	.7) To refit the transparent cover, slide the two locking pins inwards and slide the cover into place.
Washer/dispenser areas	**.8)** Do <u>not</u> spray *Microlab™ Disinfectant Spray* directly into the washer/dispenser areas as this may damage the instrument. Wipe the washer/dispenser areas with a cloth soaked in *Microlab™ Disinfectant Spray*.
	.9) The green printed circuit board must be completely dry before the instrument can be reused.
Photometer area	**.10)** Do <u>not</u> spray *Microlab™ Disinfectant Spray* directly on the photometer area as this may damage or impair the performance of the instrument. Wipe the photometer area with a lint-free cloth lightly soaked in Ethanol (70%).

NOTE
Do not use liquids containing propyl alcohol to clean the transparent cover or exit stack as they will cause stain the surfaces.

Table 8.1.3.2 - Manual Cleaning Weekly Maintenance (CONTINUED)

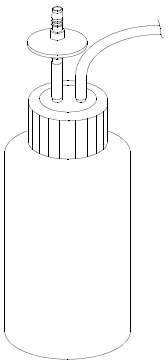
To...	Do This...
	.11) The lens block must be completely dry and free from dust and fibres before the instrument can be reused.
Reagent drawers	**.12)** See section "Reagent containers" on page 8-74.
Reagent containers	**.13)** See section "Reagent containers" on page 8-74.
Waste containers and waste caps	**.14)** See section "Waste containers" on page 8-74.
External water separator	**.15)** See section "External water separator" on page 8-74.
Wash fluid containers	**.16)** Clean all wash fluid containers (especially those which will not be used for a long period) and keep them dry.
	.17) Empty any remaining wash solution. Partially fill the container with deionized water and replace cap.
	.18) With the cap facing upwards, shake the container in the lengthwise direction for a few moments. Some liquid may leak through the thread of the cap. This is because a vent is incorporated in the thread to equalize the pressure in the container.
	.19) Control the position of the internal filter. It must be on the same side as the filling opening.
	.20) Empty the container and leave to dry.
	.21) Once a month it is necessary to rinse the wash fluid containers with *Microlab™ Detergent and Disinfectant* solution then rinse with tap water and deionized water.
Renew syringes	**.22)** The frequency of renewal of syringes and reagent containers is dependent upon the reagents being used, but as a minimum, syringes should be renewed weekly.
Renew reagent containers	**.23)** Every 4 weeks.

NOTE
Do not remove the tubing from the inside of wash fluid containers.
If a wash fluid container becomes contaminated with bacteria or fungus, it must be replaced. It is recommended to renew the wash fluid container at least once a year.

ATTENTION

Wear gloves as any liquid which is released from the tube or filter may be biohazardous.
Ensure that the venting tube at the sterile filter is free from kinks by cutting it to an accurate fit.

Table 8.1.3.2 - Manual Cleaning Weekly Maintenance (CONTINUED)

To...	Do This...
Renew sterile filter 	**.24)** The sterile filter is connected to the external water separator cap with a short piece of the venting tube. Replace the sterile filter at least every six months or as needed based on laboratory conditions or testing requirements.

Chapter 9 - 17 Reference Guide

Reference Guide Sections

9 - Reference Guide Introduction.....81
10 - ML F.A.M.E. Methods 83
11 - Daily Work Routine.....105
12 - Test Results & ML F.A.M.E. Traces.....129
13 - ML F.A.M.E. Functions & Requirements 137
14 - ML F.A.M.E. Verification.....147
15 - ML F.A.M.E. Maintenance 169
16 - Technical Specifications.....183
17 - Troubleshooting & Error Handling.....199

Chapter 9 Reference Guide Introduction

The purpose of this reference guide is to give support to the step-by-step guide (Cook Book) of the Microlab F.A.M.E. user software, version 2.0, (further referred to as ML F.A.M.E. 2.0).

A certain amount of end user basic computer understanding will be assumed throughout this manual and the assumption is that a valid user with the necessary access rights is logged in to the ML F.A.M.E. workstation.

Chapter 10 ML F.A.M.E. Methods

Table of Contents

10.1 - Overview....84
10.1.1 - Method Access Rights....84
10.1.2 - General Method Definition Limitations....84
10.2 - Method Editors....84
10.2.1 - Method Information Dialog Box....86
10.2.2 - Plate Layout Editor....90
10.2.2.1 - File Menu....90
10.2.2.2 - Edit Menu....91
10.2.2.3 - Configuration Menu....91
10.2.2.4 - Samples Menu....93
10.2.3 - Test Processing Editor....94
10.2.3.1 - File Menu....95
10.2.3.2 - Edit Menu....95
10.2.3.3 - Steps Menu....95
10.2.4 - Documentation....101
10.2.4.1 - Test Documentation - Formats....101
10.2.4.2 - Test Documentation - Jobs....102
10.2.5 - Exiting a Method....103
10.2.6 - Method Management Menu Items....103
10.2.6.1 - Check....103
10.2.6.2 - Backup....103
10.2.6.3 - Restore....103
10.2.7 - Method Verification....104

10.1 Overview

A method is a structured group of definitions, stored electronically, which enables an immunoassay test to be performed on the Microlab F.A.M.E. (ML F.A.M.E.) and includes plate layout information, processing steps definitions and documentation criteria for the test.

For information on working with methods see Cook Book Section - 3.1.1 on page 28.

10.1.1 Method Access Rights

During the method definition process individual read and write access rights can be established for the method. For further information on access rights see Reference Guide Section 13.3 on page 145.

Regardless of individual user access rights or the predefined access rights of a particular method it is impossible to perform any operations on methods under the following conditions:

1 When a method has been included in a work list that has been scheduled.

2 When the **Plan** window is open.

3 If the method is currently being used for a test running on the instrument.

10.1.2 General Method Definition Limitations

NOTE
While editing a method it is not possible to change the logged in ML F.A.M.E. operator.

❒ A maximum of 100 methods can be stored in the database.

❒ A method cannot exceed 50 processing steps.

❒ A maximum of 400 fluids (including both method-specific and global fluids) can be defined in the ML F.A.M.E. Software.

The ML F.A.M.E.'s method definition supports methods which will provide only the OD (optical density) values for the samples of a test. Further result interpretation must to be carried out *externally* to the system.

10.2 Method Editors

The method editors are used to work with methods stored on the ML F.A.M.E. database and are divided into five main areas as follows:

❒ **Method Information** dialog box - is used to define general method information and is the first step in the method definition.

- ❒ **Layout Editor** - used to define plate dimensions and sample layout and arrangement.
- ❒ **Test Processing Editor** - used to define test processing steps.
- ❒ **Documentation** - used to define documentation criteria.
- ❒ **Barcode Mask** dialog box - used to establish a barcode mask.

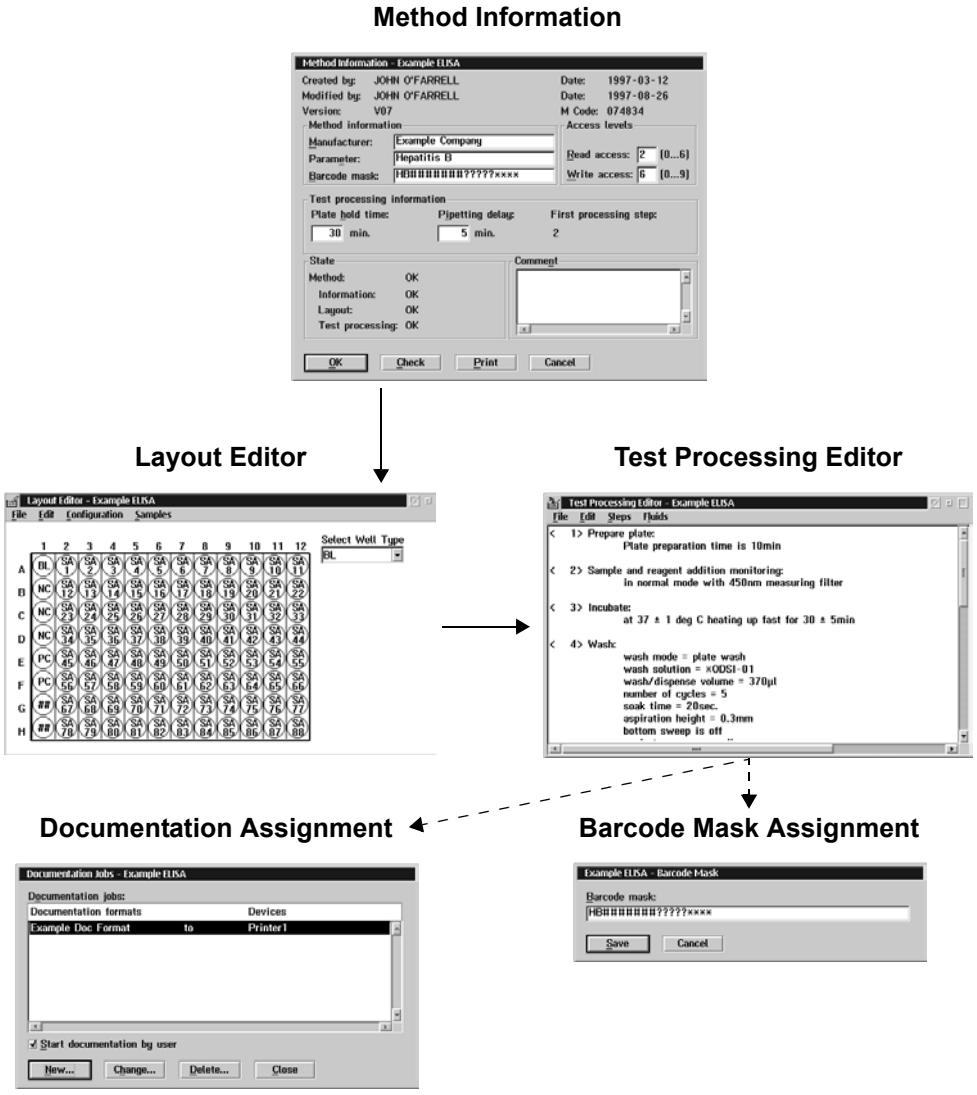


Figure 10.1 Method Editors Process Flow

10.2.1 Method Information Dialog Box

The **Method Information** dialog box is the first step in the method definition process and is used to define the general information for the method and to display the processing status of the method, i.e. if the method has been checked and is processible.

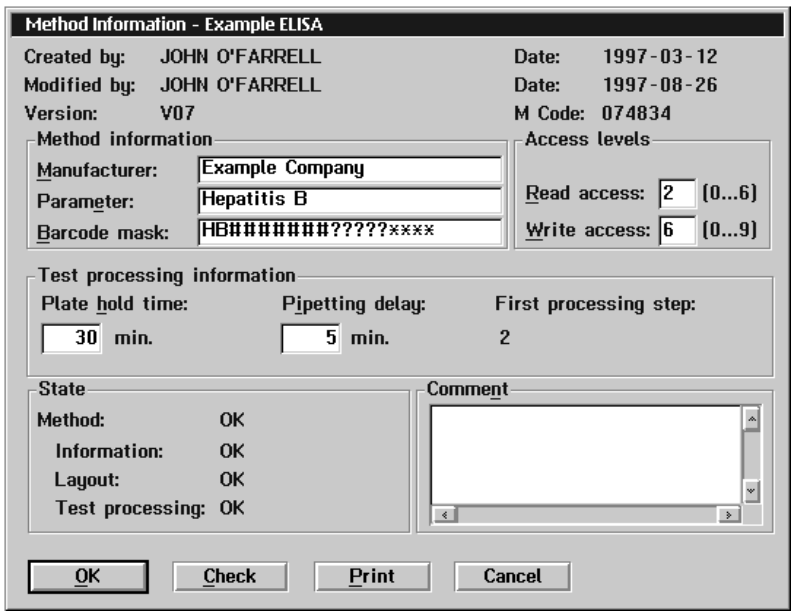


Figure 10.2 Method Information Dialog Box

- **Created by**: This is the name of the user logged-in when the method was created. Directly across the dialog box from this entry is the associated creation date.

- **Modified by**: This is the name of the user logged-in when the method was last modified. Directly across the dialog box from this entry is the associated modification date.

- **Version**: Each time the method is saved this number is increased by one.

- **M Code**: When a new method is defined, it is assigned a unique security code (designated M Code). Similarly, when an existing method is edited, a new security code (M Code) is assigned to it.

  When the results of a test are generated, the M Code of the method used at the time of the test is recorded in the test results.

- **Manufacturer**: This entry is freely definable by the ML F.A.M.E. oprator and has no systems relevance. Enter the manufacturer's name in this entry field, i.e. *Example Company*.

- **Parameter**: Again, this entry is freely definable by the ML F.A.M.E. oprator and has no systems relevance. Enter the type of test here, i.e. *Hepatitis B*.

NOTE
It is also possible to assign or edit the barcode mask using the Method menu - Edit sub-menu - Barcode mask.

NOTE
Each method has to have a unique barcode mask, i.e. no two methods may have the same barcode mask.

❒ **Barcode Mask**: The barcode mask defines the basic structure of the plate barcode. Two types of character are defined in the barcode mask:

- ❍ *Barcode-Specific Characters* - the use of barcode-specific characters will identify each barcode as being of the same method or from the same manufacturer.
- ❍ *Barcode Wildcards* (variables) - the use of variables or "wild-cards" that hold information like the test kit lot number, plate number, test number, etc.

Barcode mask criteria are given in the following table:

Maximum number of characters:	34	
Forbidden character:	%	
Wildcard characters:	?	Mask character for test number (numerics only).
	#	Mask character for kit lot number (alpha-numeric).
	*	Mask character for any other characters which may vary from one barcode to another (alpha-numeric).

The following restrictions apply to barcode mask definitions:

- ❍ A barcode mask may *not* be made-up of only wildcard characters.
- ❍ The wildcards '?' and '#' can only appear in one group, i.e. identical wildcards must not be separated by other characters. The '*' wildcard *can* be defined in different places of the barcode mask.
- ❍ Barcode masks of identical length must be different in at least one fixed character. The complete length of the fixed part of the barcode mask is used for plate identification.

Valid and invalid masks:

HAM#######?????**** - valid

These characters appear in every barcode | 7 characters for kit lot number | 5 characters for test number | 4 characters for any other

HAM##??###??#??**?** - invalid (interdispersed wildcards)

Examples of valid barcodes:

- ✔ HIV-BM-?????
- ✔ T4?????Pa####
- ✔ HP1????*****'
- ✔ AB##
- ✔ A?##

Examples of invalid plate barcodes:

✘ ABC??D??	Wildcard '?' separated by another character
✘ ABC??##??	Wildcard '?' separated by wildcard '#'
✘ ABC50%T??K##	Contains character not allowed (%)
✘ ##??****	Consists exclusively of wildcards
✘ ABC** ***and*** AB###	Barcode mask not unique

NOTE
For users that print their own barcodes please See section 16.3 on page 16-191 for further information.

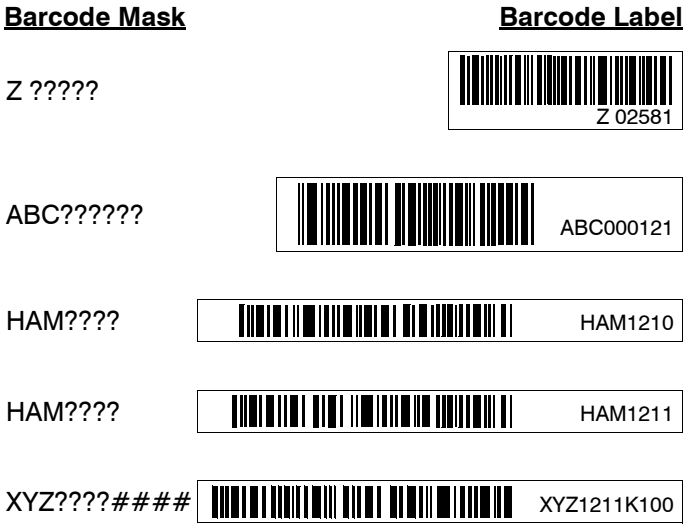


Figure 10.3 Barcode Masks and their Corresponding Barcode Labels

❒ **Access Levels**:

- ❍ *Read Access:* This specifies the access level a user must have to be able to open the method.
- ❍ *Write Access:* This specifies the access level a user must have to be able to edit or modifying the method.

❒ **Test Processing Information**:

❍ *Plate Hold Time:* Maximum time between the time stamp from the barcode file and the “First processing step” defined in the Method. This time frame will be checked by the ML F.A.M.E. software and if exceeded the plate will be rejected.

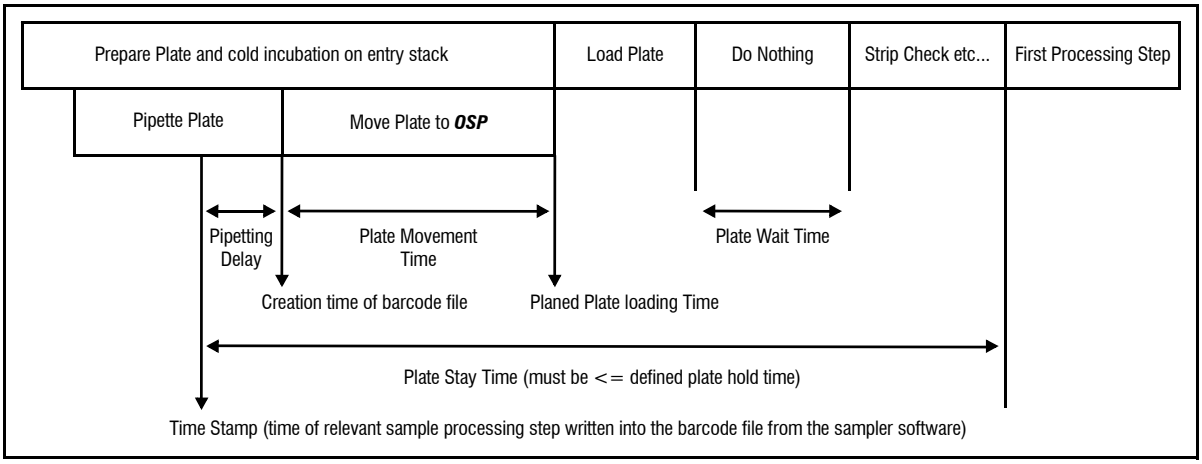

Prepare Plate and cold incubation on entry stack
Load Plate
Do Nothing
Strip Check etc...
First Processing Step
Pipette Plate
Move Plate to OSP
Pipetting Delay
Plate Movement Time
Plate Wait Time
Creation time of barcode file
Planed Plate loading Time
Plate Stay Time (must be <= defined plate hold time)
Time Stamp (time of relevant sample processing step written into the barcode file from the sampler software)

Figure 10.4 Plate Hold Time

❍ *Pipetting Delay:* The time span between pipetting the first and last well of a plate can be rather large, especially for complex sample pipetting sequences. To compensate for this difference from the first well pipetted to the last, an average can be set with this command.

❍ *First Processing Step:* This specifies which is to be the first step used in the calculation of the end of the plate hold time (See section 10.2.3.2 on page 10-95).

❒ **State**: This is the Check State of the method and includes:

NOTE
A method that returns warnings when checked may still be run while a method returning errors cannot be run.

❍ *Information:* whether the method information has passed the checking criteria.

❍ *Layout:* whether the plate dimensions and layout have passed the checking criteria.

❍ *Test Processing:* whether the method’s processing steps have passed the checking criteria.

NOTE
Unless a method has a state of OK in all sections, it is not possible to use the method for a run.

❒ **Check** push button: This starts a check of all method elements against a predefined criteria displaying an error and error information where applicable.

10.2.2 Plate Layout Editor

The **Plate Layout Editor** allows the definition of the plate layout, plate configuration and all plate-related values.

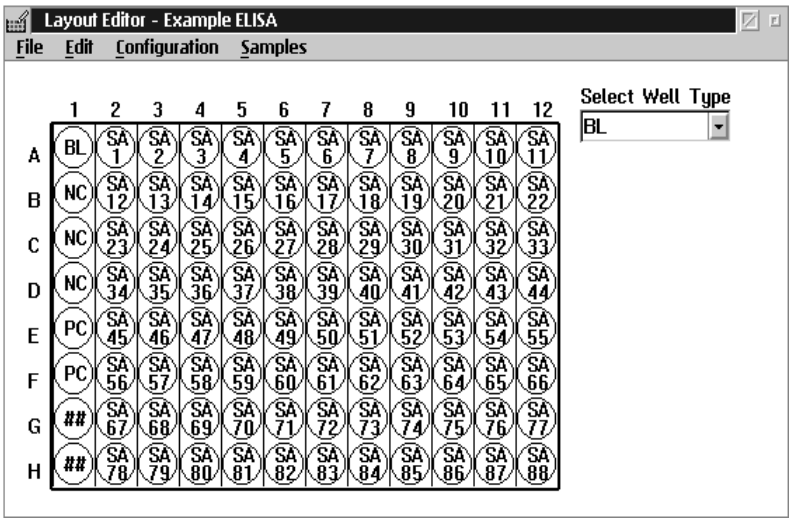

Layout Editor - Example ELISA
File Edit Configuration Samples
Select Well Type
BL
1 2 3 4 5 6 7 8 9 10 11 12
A BL SA1 SA2 SA3 SA4 SA5 SA6 SA7 SA8 SA9 SA10 SA11
B NC SA12 SA13 SA14 SA15 SA16 SA17 SA18 SA19 SA20 SA21 SA22
C NC SA23 SA24 SA25 SA26 SA27 SA28 SA29 SA30 SA31 SA32 SA33
D NC SA34 SA35 SA36 SA37 SA38 SA39 SA40 SA41 SA42 SA43 SA44
E PC SA45 SA46 SA47 SA48 SA49 SA50 SA51 SA52 SA53 SA54 SA55
F PC SA56 SA57 SA58 SA59 SA60 SA61 SA62 SA63 SA64 SA65 SA66
G ## SA67 SA68 SA69 SA70 SA71 SA72 SA73 SA74 SA75 SA76 SA77
H ## SA78 SA79 SA80 SA81 SA82 SA83 SA84 SA85 SA86 SA87 SA88

Figure 10.5 Layout Editor Window

For further information on the **Layout Editor** see Cook Book Section - 3.1.1 on page 28.

10.2.2.1 File Menu

The **File** menu allows the user to control the management functions of the **Plate Layout** Editor.

- ❒ **Check Layout** - when selected, this menu choice checks to make sure all defined well types have been used. A dialog box will display an error message if applicable.
- ❒ **Save Method** - saves the method to the ML F.A.M.E. database.
- ❒ **Switch to Test Processing** - minimizes the **Plate Layout Editor** and opens the **Test Processing Editor**.
- ❒ **Method Information** - opens the **Method Information** dialog box for the current method.
- ❒ **Save and Switch to Test Processing** - saves the **Plate Layout Editor** information defined and opens the **Test Processing Editor**.
- ❒ **Print** - prints on the default printer a graphical representation of the **Plate Layout** as defined for the current method.
- ❒ **Close Editor** - shuts down the **Plate Layout Editor**.
- ❒ **Exit Method Editor** - shuts down all method related editors and related dialog boxes.

10.2.2.2 Edit Menu

The **Edit** menu allows the user to work with well types.

NOTE
Well type names can consist of only two alpha characters. No numerics are allowed.

❒ **Edit Well Types** - this menu choice displays the **Edit Well Types** dialog box allowing the user to define new and delete existing well types, the plate layout can also be checked.

Here is an example of possible well types:

- ❍ NC (default Negative Control type)
- ❍ PC (default Positive Control type)
- ❍ SA (default SAmple type)
- ❍ Keep Empty (##). This indicates that wells of this type serve no function in a test and no reagents should be dispensed into them.

If other well types are required they must be defined manually (See Cook Book page - 28).

NOTE
It is not possible to define individual wells as samples (default abbreviation **SA**) as all wells otherwise not defined are interpreted as sample containing wells and automatically filled as per the defined criteria.

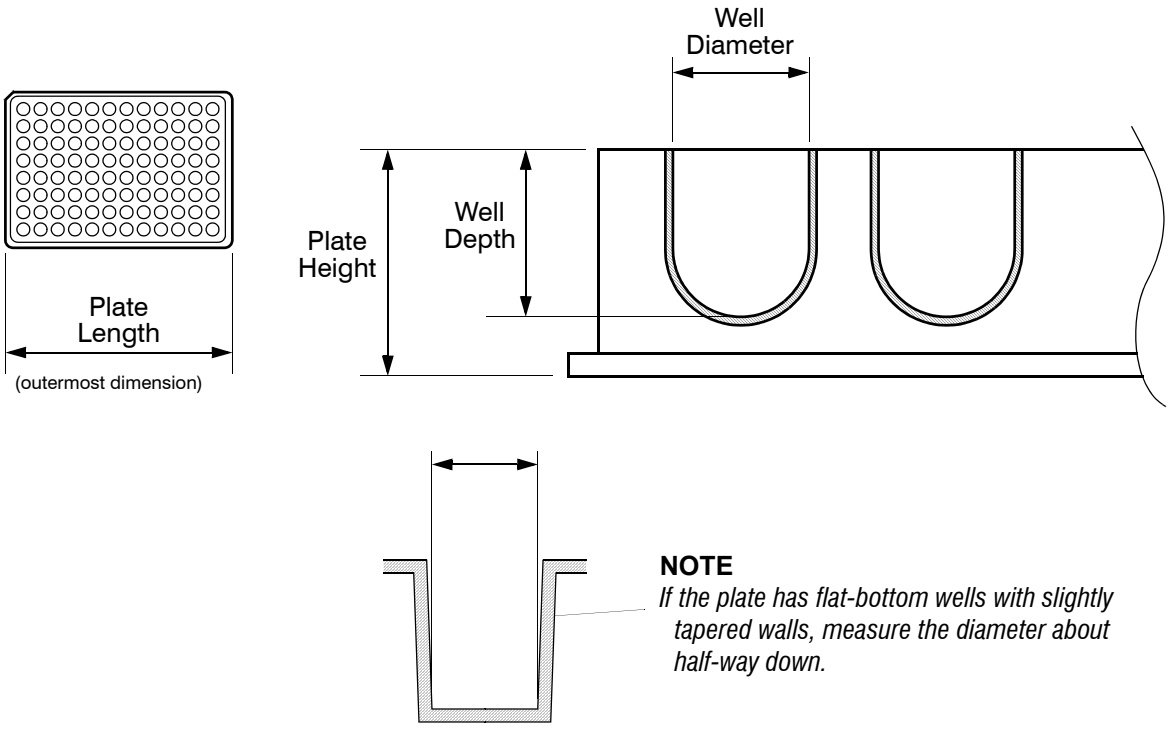
❒ **Clear Layout** - clears the plate of all definitions.

10.2.2.3 Configuration Menu

ATTENTION
The plate dimensions specified in the plate configuration must correspond exactly to the dimensions of the plate to ensure error-free washing and dispensing. Erroneous plate dimensions may cause contamination or spillage during wash and dispense steps.

Use the **Configuration** menu to define the characteristics of the plate being used. The following data must be specified:

❒ **Set Plate Dimensions** - enter the plate length, plate height, well diameter and well depth in the appropriate entry fields. Figure 10.6 explains exactly what these dimensions are. *This step is mandatory*.



NOTE
If the plate has flat-bottom wells with slightly tapered walls, measure the diameter about half-way down.

Figure 10.6 Plate Dimensions

ATTENTION
Use the dial caliper supplied with the instrument to measure the plate dimensions.

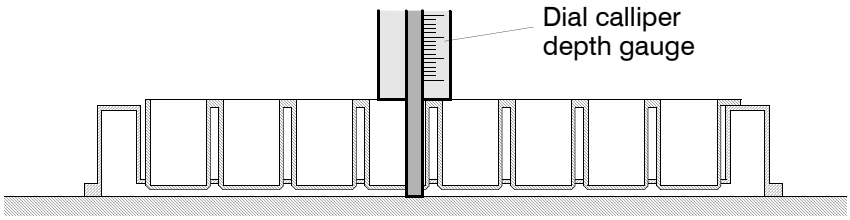


Figure 10.7 Method for Measuring Plate Height

- **Strip direction** (either horizontal or vertical) - this feature is used for plates with removable strips and defines in which direction the strips run.

- **CAg/Ag Coating** - defines whether the strips are alternately Control Antigen/Antigen (CAg/Ag) coated. This feature is generally used only in very specialized applications.

10.2.2.4 Samples Menu

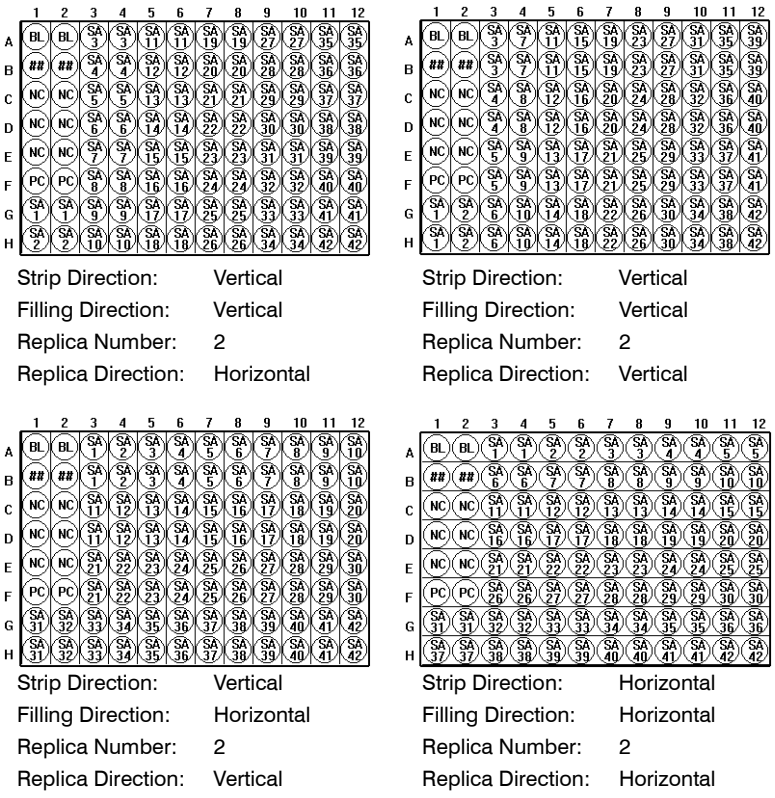
The **Samples** menu is used to define the following:

- ❒ **Arrange Samples** - once all control well types and layout definitions are completed, use this command to fill the remainder of the plate with samples.
- ❒ **Sample Filling Direction** - (either left to right (horizontal) or top to bottom (vertical)).

NOTE
The replica number applies only to sample well types.
Control and blank wells can only be replicated manually.

- ❒ **Sample Replica Number.**
- ❒ **Replica Direction** - (either left to right (horizontal) or top to bottom (vertical)).

This menu is also used to automatically rearrange the sample layout.



Strip Direction:	Vertical	Strip Direction:	Vertical
Filling Direction:	Vertical	Filling Direction:	Vertical
Replica Number:	2	Replica Number:	2
Replica Direction:	Horizontal	Replica Direction:	Vertical
Strip Direction:	Vertical	Strip Direction:	Horizontal
Filling Direction:	Horizontal	Filling Direction:	Horizontal
Replica Number:	2	Replica Number:	2
Replica Direction:	Vertical	Replica Direction:	Horizontal

Figure 10.8 Example Sample Layouts

Before exiting the layout editor, all unused well types must be deleted. For instance, if no NC well types are used in the layout, all reference to this well type must be deleted, using the delete function in the **Edit** *menu.*

Defining an Error-Free Plate Layout Compatible with Microlab AT/ATplus 2

NOTE
Sample wells that are not pipetted by the Microlab AT/Microlab ATplus 2 will be flagged as "not pipetted" and will not be processed by the ML F.A.M.E..

If a *Microlab AT* or *Microlab ATplus 2* is being used for plate sample distribution and the barcode files are transferred to the ML F.A.M.E. workstation, the following points should be considered when defining the plate layout:

- ❒ Define the location of controls as they are pipetted in the Sunrise/Sunplus definition.
- ❒ Use a replica number consistent with the pipetting procedure defined in Sunrise/Sunplus (e.g. replica number = 2 means two wells per sample).
- ❒ Ensure that the replica direction corresponds with the Sunrise/ Sunplus definition.
- ❒ Wells which are never pipetted by the Microlab AT/ML ATplus 2 should be defined as "Keep Empty".

10.2.3 Test Processing Editor

The **Test Processing Editor** allows the user to define all the processing steps for a method. Each step, incubation duration and temperature, wash procedure and photometer settings, etc., can be defined using this window and its dialog boxes. In addition to these steps, the **Fluids** menu allows reagents and wash fluids to be defined and edited.

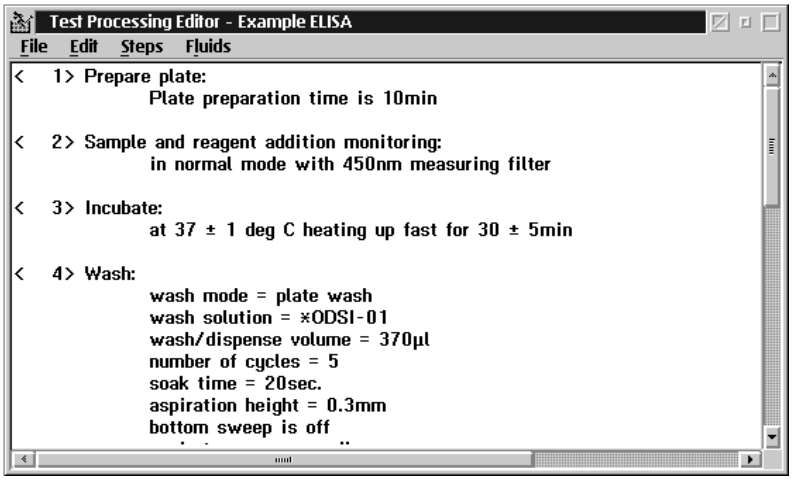

Test Processing Editor - Example ELISA
File Edit Steps Fluids
< 1> Prepare plate:
Plate preparation time is 10min
< 2> Sample and reagent addition monitoring:
in normal mode with 450nm measuring filter
< 3> Incubate:
at 37 ± 1 deg C heating up fast for 30 ± 5min
< 4> Wash:
wash mode = plate wash
wash solution = *ODSI-01
wash/dispense volume = 370µl
number of cycles = 5
soak time = 20sec.
aspiration height = 0.3mm
bottom sweep is off

Figure 10.9 Test Processing Editor Window

10.2.3.1 File Menu

- ❒ **Check Layout and Processing Definition**.
- ❒ **Save Method** - stores the method in the ML F.A.M.E. database.
- ❒ **Switch to Plate Layout Editor** - minimizes the **Test Processing Editor** and opens the **Plate Layout Editor**.
- ❒ **Method Information** - opens the **Method Information** dialog box for the current method.
- ❒ **Save and Switch to Plate Layout Editor** - saves the **Test Processing Editor** information defined and opens the **Plate Layout Editor**.
- ❒ **Print** - prints on the default printer test processing information as defined for the current method.
- ❒ **Close Editor** - shuts down the **Test Processing Editor**.
- ❒ **Exit Method Editors** - shuts down all method related editors and related dialog boxes.

10.2.3.2 Edit Menu

The **Edit** Menu has three choices:

- ❒ **Change** - allows the user to change the settings of the selected step.
- ❒ **Delete** - allows the user to delete the selected step.

NOTE
The default first processing step is set to 0 (zero) meaning that the ML F.A.M.E. operator must define it manually, otherwise an error is returned when the method is checked.

- ❒ **Set First Processing Step** - displays a dialog box allowing the user to define which step in the definition is the first relevant step to be processed on the ML F.A.M.E. (used to calculate the plate hold time).

10.2.3.3 Steps Menu

The **Steps** menu allows the user define the required processing steps, for the current method, from the nine different processing steps available for use with the ML F.A.M.E..

- ❒ **Prepare Plate...** -

NOTE
This step can be defined only once within a method and is always the first step of a method, if included.

  - ❍ The approximate plate preparation time. This information is necessary for scheduling. The operator can then be instructed when to start preparing the plates. Sample preparation has to be carried out externally to the system.

- ❒ **Incubate... -** This option is used to define the incubation step.

  - ❍ *Type of incubation*:
    This can be either ambient or temperature controlled.

- *For ambient incubation*:
  Ambient temperature upper and lower limits: These define the allowable temperature range for ambient incubation required for the assay.
- *For temperature-controlled incubation*:

  Temperature: Required temperature.

  Temperature tolerance: The permissible variation in incubation temperature.

  Heating up: (either slow, medium or fast) of the incubator slot. The heating up rate is the speed at which an incubation slot is raised to its preset temperature after a plate has been inserted (an incubation slot loses temperature when its door is opened).

NOTE
For short incubation times (approx. 30 minutes) or for heating-up characteristics similar to a water bath, use **fast** heating up.

- *Incubation time*: Duration of Incubation.
- *Tolerance time*: The permissible variation in the incubation time.

❒ **Wash... -** This option is used to define how the plate is to be washed.

The following data must be specified:

- *Wash solution name.*
- *Wash mode, Either:*

  Strip wash: The plate is washed three strips at a time, i.e. if there are 2 wash cycles, 3 strips of 8 wells are washed twice, then the next 3 strips twice, then the next 3 twice, etc.

  Plate wash: Each wash cycle is completed over the whole plate before the next cycle, i.e. if there are 2 wash cycles, the entire plate is washed 3 strips at a time and then immediately again for the second cycle.

  Dispense Only: With this mode wash solution is only dispensed into the wells.

NOTE
When setting the wash volume, make allowance for the well volume and do not overfill the wells. Avoid creating a convex meniscus. If a higher volume is required to wash the well (e.g. 500 µl), the option “Continuous wash” can be used to define the additional volume needed (e.g. specify 300 µl for the Wash/Disp. volume and 200 µl for the additional volume).

- *Wash/Disp. Volume*: Specifies the amount of solution to be dispensed during washing.
- *Number of Cycles*: Specifies the number of times the wash cycle should be repeated.
- *Soak Time*: Specifies the time the dispensed wash solution should be left in the plate before aspiration.

NOTE
If a negative aspiration height is specified, a warning message will appear on the screen. A negative aspiration height causes the aspirating needles to come in contact with the bottom of the wells of the plate, under the weight of the manifold and manifold coupling.

- *Aspiration Height*: Specifies the distance between the aspiration needle and the bottom of the well during the aspiration cycle.

  There are three additional wash options as follows:

- *Continuous Wash*: With this option dispensing and aspiration take place simultaneously at the top of the well. This option requires the following data to be specified:

  Additional volume: The volume of wash fluid to use in addition to that specified for a normal wash. Since dispensing and aspiration take place simultaneously, this can be greater than the well volume.

- *Bottom Wash*: This is the same as continuous wash except that the aspiration needles are positioned near the bottom of the wells. This option requires the following data to be specified:

  Additional Volume: The volume of wash fluid to use in addition to that specified for a normal wash. Since dispensing and aspiration take place simultaneously, this can be greater than the well volume.

  Height: The distance between the bottom of the aspirating needle and the bottom of the well.

ATTENTION
If using bottom sweep, specify an aspiration height ≥ 0.3 mm to prevent the aspirating needles from scratching the bottom of the plates. Check for scratching with a verification run (see section - 10.2.7 on page - 104).

- *Bottom Sweep On*: With this option the plate is moved backwards and forwards during washing to minimize the wash solution left in the wells. This option is only possible when using plates with flat-bottom wells.
- Pump Power: The following data must be specified:

  Aspirate Power (either low, medium or high).

  Dispensing Power (either low, medium or high).

  Aspirate Power During Dispensing (either low, medium or high).

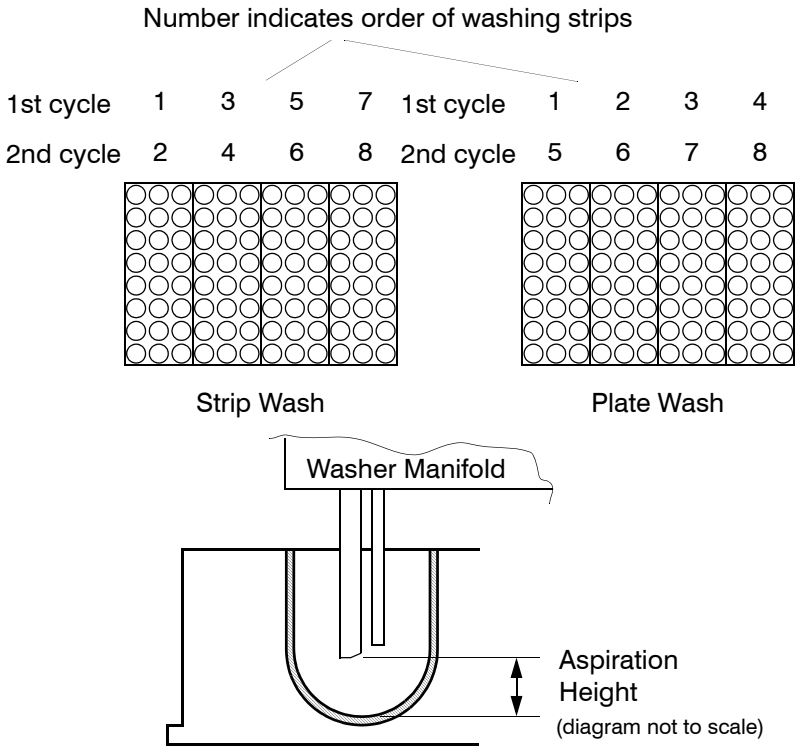

Number indicates order of washing strips
1st cycle 1 3 5 7
2nd cycle 2 4 6 8
1st cycle 1 2 3 4
2nd cycle 5 6 7 8
Strip Wash
Plate Wash
Washer Manifold
Aspiration Height
(diagram not to scale)

Figure 10.10 Explanation of Strip Wash and Plate Wash (2 cycle wash) and aspiration height

❒ **Dispense... -** this step defines the criteria for reagent dispensing.

The following data must be specified:

- ❍ Reagent name.
- ❍ Into which well types (PC, NC, etc.).
- ❍ Dispense volume.
- ❍ Dispense speed (either very slow, slow, medium or fast).
- ❍ Aspirate speed (either very slow, slow, medium or fast).

❒ **Sample and Reagent Addition Monitoring (SRAM)...**

This step starts a photometric reading of the plate and is usually included after a reagent dispense step for assays in which the manufacturer added dyes to the various reagents. Evaluation of the photometric results can determine whether the reagent dispensing was successful or not.

SRAM data evaluation criteria can be defined using the Range Check section of the SRAM dialog.

NOTE
The inclusion of a **S**ample and **R**eagent **A**ddition **M**onitoring step within a method should be given some consideration as this option can have **effects on the instrument's throughput** since additional transport and photometric read steps will become necessary to process such a step.

A sample and reagent addition monitoring step can be included in the Test Processing definition as often as desired and at any time during the processing sequence.

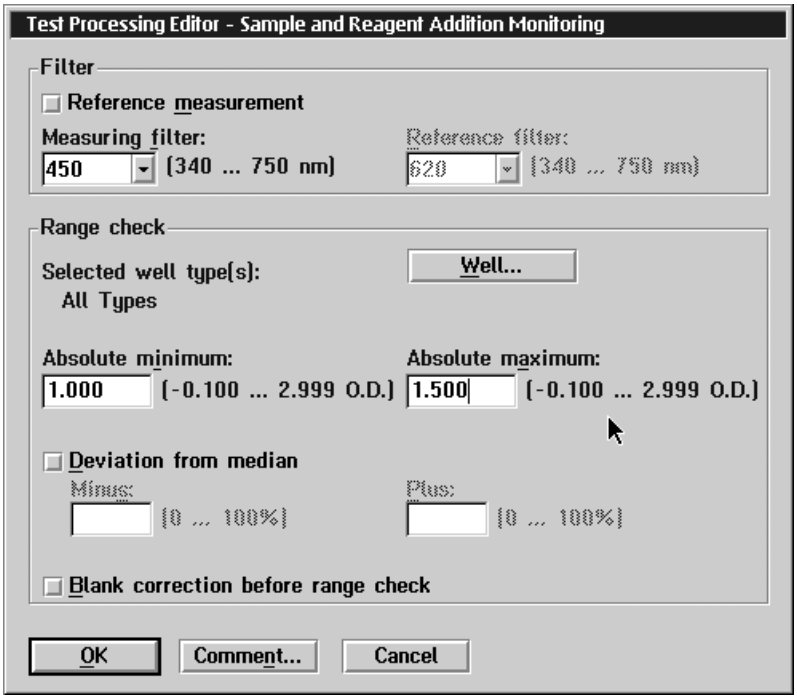


Figure 10.11 Test Processing Editor - SRAM dialog box

The following filter data can be specified for each step:

- *Type of measurement* - either single wavelength measurement mode or reference measurement mode.
- *Photometer filter wavelength(s)* - for one or, in case of reference measurement mode, two filters.

NOTE
The range check will happen real time during the run. However, it will have no influence on a test's processing. Any well errors will be recorded in the trace entry.

The following range check data can be specified for each step:

- *Select well type(s)* - By selecting the **Well**... push button it is possible to specify which well types will be used in the range check.
- *Absolute Minimum and Absolute Maximum* - entry fields allow the ML F.A.M.E. operator to define the check range within which the OD's are valid.
- *Deviation From Median* - check button, the ML F.A.M.E. operator can set the percentage from the median at which the well is then interpreted as correctly dispensed. This is an additional step performed after the range check.
- *Blank Correction Before Range Check* - check box will, when selected, perform a blank correction before starting the range check. The mean of all *valid* wells defined as "Blank" will be subtracted for the value of all other wells. If the blank correction option is selected, "Blank" wells may not be included in the range check.

- *Comment* - push button allows the ML F.A.M.E. operator to add a comment. This comment will be displayed in the **SRAM Error** dialog box.

NOTE
A mix step should be specified before photometric measurement (**Read...** step) or after dispensing reagent into plate.

❒ **Mix... -** use this step to agitate the plate for a given time.

The following data must be specified:

- *Mix intensity* - either low (5 Hz), medium (7 Hz) or high (11Hz).
- *Mix time*.

NOTE
The inclusion of a **Re-Identify** step within a method should be given some consideration as this option can have an **effect on the schedule** since additional transport steps and plate barcode read steps will become necessary to process such a step.

❒ **Re-Identify...**

This step results in a re-identification of the plate barcode during processing and is used to ensure that no plate mix-ups occur during processing. A re-identify step can be included in the test processing definition as often as desired and at any time during the processing sequence.

❒ **Read... -** this step is used for photometric measurement. The following data has to be specified:

- *Measuring filter wavelength.*
- Whether a reference measurement is required, and if so...
- *...Reference filter wavelength.*

❒ **Exit Plate...**

This step is used if the plate has to be removed from the instrument for external processing. When this step is executed, the plate is sent to the manipulation position allowing it to be removed.

It is not then possible to continue with the method after removing the plate.

Fluids

The **Fluids** menu allows the definition of all fluids which are required to process a test of this method. Fluids can be wash solutions or reagents.

Two options are given in this menu:

❒ **Edit Method specific...**

❍ This option displays a dialog box allowing the user to select and change already defined, add new or delete existing method specific fluids.

When the **Change** or **Add** options are selected the **Edit Method Specific Fluid** dialog box is displayed:

here the type of fluid is defined with the fluids name, dual components if applicable i.e. for a fluid that uses two components mixed together,

NOTE
Verification of fluids is possible only in installation mode “Active Kit Lot Check”.

whether the fluid must be verified i.e. matching the fluid with the registered components for that fluid,

the preparation time,

the fluids stability state and stability duration.

there is also a comment field.

❒ **Edit Global...**

❍ This option accesses a dialog box allowing the user to select and change already defined, add new fluids or delete existing global fluids.

Change...
If the global fluid is used by another method(s) a dialog box will be displayed showing the method(s) and the user is asked to confirm whether to continue or not.

Delete...
It is not possible to delete a global fluid if it is used by another method(s) stored on the ML F.A.M.E. database.

10.2.4 Documentation

A method’s documentation is defined in two parts - the first controls the definition of a method’s documentation formats the second is the actual way it is handled.

10.2.4.1 Test Documentation - Formats

NOTE
A documentation format is non-method-specific. One documentation format can included in a documentation job and be used across many different methods.

A test’s documentation format determines the information that will appear in the test’s final documentation.

A number of different options can be defined in the **Documentation Format** dialog box. These include:

❍ *Traces* - well trace and test trace, use these check buttons to specify if the documentation format will include individual well information and test trace information.

- *Priority* - three priority categories can be set, these specify the severity of information to be included in the documentation:
  Note: all traces are included.
  Warnings: trace messages with the severity 'Error' and 'Warning' are included.
  Errors: trace messages with severity 'Error' are included.
- *On printouts only* - specifies which information appears in printouts and includes:

  Table of non-samples, i.e. controls and blanks.
  Table of samples.
  Plate-oriented information, i.e. graphical representation of a microplate with the test's data displayed in it.

10.2.4.2 Test Documentation - Jobs

A test documentation job determines where a test documentation format for a specific method is sent. All test documentation jobs associated with a method are listed in the **Documentation Jobs** dialog box. In Figure 10.12 a job is shown which sends the documentation protocol called "Example Doc Format" to the device called "Printer1". In this case, the destination is "Printer1" but could be a host computer.

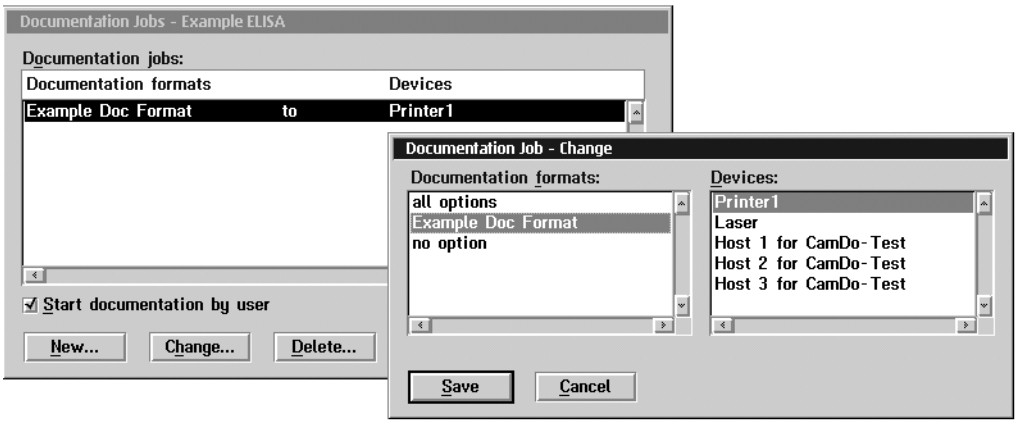


Figure 10.12 Edit Test Documentation Job Dialog Boxes

A default feature of the ML F.A.M.E. *software allows a method-independent documentation job to be executed whenever any test of any method type is finished on the Summit Processor for further information see Cook Book Section - 3.1.2 on page 37.*

10.2.5 Exiting a Method

ATTENTION
When leaving the method editor, the user is prompted whether the method should be checked and verified. If the user declines or if the method does not check out without errors, then the method cannot be used on the ML F.A.M.E..
It is also possible to check the method at a later date and then if it checks out without errors it can be used.

Exit a method in any of the following ways:

Select **Exit editing** from the **Methods** menu.

Select **Exit method** from the **File** menu of any of the method editing windows (Plate Layout and Test Processing).

To close a specific method editing window, select the **Close** choice from its **Window Control** menu (to display the **Window Control** menu, click on the Title Bar Icon - for further information on closing windows please refer to the OS/2 documentation supplied with the version of OS/2 installed on the ML F.A.M.E. workstation).

10.2.6 Method Management Menu Items

The method management information supplied below is a technical reference. For further information on method management see Cook Book Section - 3.1.3 on page 38.

10.2.6.1 Check

The **Check** menu item performs a verification of the entire method currently open. Any errors encountered will be listed in a dialog box. Errors such as incomplete definitions will be displayed. Only methods which are “checked and ok” or methods with just warnings can be used for running tests on the instrument. If no method is currently open, one can be selected from a list for checking.

10.2.6.2 Backup

The **Backup...** menu choice allows a method definition to be archived onto another device such as a floppy disk or any other drive (LAN, etc.). The method to be backed up has to be selected and the backup path specified. As default, the backup directory defined in the **Software Presettings** dialog box is displayed.

Methods can only be backed up individually, i.e. one method at a time.

10.2.6.3 Restore

NOTE
Only one method can be restored at a time using the **Restore...** function, i.e. it is not possible to specify a batch of methods to restore.

The **Restore...** menu item allows an archived method definition to be re-loaded from a device such as a floppy disk or any LAN drive, into the database. The path of the archived method has to be specified. As default, the default directory as defined in the **Software Presettings** dialog box is displayed.

Any restored method should also be verified before being used for real tests, see section 10.2.7 on page 10-104. If the restored method’s barcode mask is not unique within the methods currently stored on the instrument’s database, a message is displayed in which a new barcode mask must be assigned.

10.2.7 Method Verification

ATTENTION

After a new method has been created with the method editor, a verification run should be performed. Deionized water containing 0.9 % NaCl should be used as a substitute for all reagents and wash solutions.

Before using any newly created method for routine test purposes, a comparison study between the method previously used and the new one must be carried out to ensure that the processing and data evaluation of both methods produce equal results.

The entire test should be visually overseen by the method programmer to ensure that all steps are executed correctly and that the right values for wash volumes and reagent volumes have been specified. It is also advisable to check for errors in the programming of the order of processing steps. Wrong parameters may result in fluid being spilled from plates onto the instrument's transport system.

Chapter 11 Daily Work Routine

Table of Contents

11.1 - Overview - Daily Work Routine....106
11.1.1 - Elements of a Test Run....106
11.1.2 - Work Menu....107
11.2 - Kit Lot Editor....108
11.2.1 - Menu Choices....108
11.3 - Work List Manager....109
11.3.1 - Menu Choices....110
11.3.2 - Scheduling a Work List....111
11.4 - The Plan Window....112
11.4.1 - Menu Choices....112
11.4.2 - Test Window....113
11.4.3 - Time Bar....113
11.4.4 - Fluid Window....114
11.4.5 - Changing a Work List....114
11.5 - Fluid Handling....116
11.6 - Assignment Editor....117
11.6.1 - Fluid Container Barcode Reservation....117
11.6.2 - Reserved Bar Codes....117
11.7 - Starting a Run....118
11.7.1 - Fluid Handling - General Remarks....118
11.7.2 - Inserting the Reagent Containers into the Carousel....119
11.7.3 - Using Reagent Container Carousels....120
11.7.4 - Fluid Handling for Stable Reagents....120
11.7.5 - Loading of Unstable Reagents....121
11.7.6 - Loading of Wash Solutions....121
11.7.6.1 - Wash Solution Loading Dialog Box....122
11.7.7 - Plate Preparation and Sample Pipetting Information....123
11.7.8 - Plate Loading....123
11.8 - Changing a Run....126
11.8.1 - Un-schedule....126
11.8.2 - Reschedule....126
11.9 - Aborting a Plate or Run....127
11.9.1 - Aborting Plate....127
11.9.2 - Aborting a Run....127
11.10 - Finishing a Run....128

11.1 Overview - Daily Work Routine

The daily work routine consists of all the day to day operation of the Microlab F.A.M.E.

Included in this are:

- ❒ **System Start-up**
- ❒ **Defining and Editing Stack Types**
- ❒ **Defining and Editing Work Lists**
- ❒ **Fluid Handling**
- ❒ **Scheduling and Un-scheduling Work Lists**
- ❒ **Starting the Test Run**
- ❒ **Plate Processing**
- ❒ **System Shut-down**

These are the main elements that make up the daily work routine.

Although there are other necessary procedures i.e. maintenance, etc.,... these are explained in separate sections.

11.1.1 Elements of a Test Run

To execute a test run, a work list defining the work-load (i.e. number of plates and methods to use) must first be created.

Below are the elements associated with executing a test run.

- ❒ **Stack Types** are the basic building blocks with which the work-load is made-up.
  A stack type is an electronically stored list containing reference information for up to four plates and the methods associated with them.
  This list corresponds directly to a physical entry stack to be loaded with this quantity of plates and requiring the specified methods. This is the basic loading unit for the system.
  Stack types can be made up of various methods and do not have to be of only one type of method, these stack types can then be stored on the ML F.A.M.E. database.

- ❒ A **Work List** is a group of stack types and their projected loading times. Only one work list can be scheduled to run on the instrument at any one time.

❒ The **Plan** window is the next step in the routine execution of a test run. After scheduling a work list the **Plan** window displays a graphical representation of the various methods (with barcode and location information etc.) scheduled to run and is updated constantly when events occurred that have impact on the processing of a test run.

❒ **Action List** is a document type file generated by the ML F.A.M.E. software which provides a timetable of actions and steps required of the ML F.A.M.E. operator to execute the test run and is based on the work-load defined in the work list. This list is created after the work list is scheduled and can only be printed out (i.e. is not displayed on the monitor); the action list is not updated for any changes in the work list.

11.1.2 Work Menu

The **Work** menu in the **Main** ML F.A.M.E. window allows access to the functions necessary to execute a test run on the Summit Processor.

❒ Available menu choices include:

- ❍ **Work List Manager** - launches the **Work List Manager** window (see page - 109 for general information and see Cook Book Section - 4.1.4 on page 45 for information on work list handling).
- ❍ **Stack Types** - allows access to sub-menu choices relating to the definition of new, edit existing, deleting or printing stack types (see Cook Book Section - 4.2.1 on page 43).
- ❍ **Assignment Editor** - allows the allocation of barcodes to fluids and specifying fluid locations (see page - 116 for general information and see Cook Book Section - 4.1.6 on page 50 for information on fluid handling).

NOTE
This option is only available if the Kit Lot Documentation installation option was selected.

- ❍ **Kit Lot Editor** - allows the creation of new, editing of existing kit lot files in the defined path. Kit lots for existing methods or global fluids can be created, edited or deleted.

11.2 Kit Lot Editor

NOTE
This option is only available if the Kit Lot Documentation installation option was selected.

The **Kit Lot Editor** window displays a list of methods and global fluids (indicated with a preceding asterisk) with the following associated information:

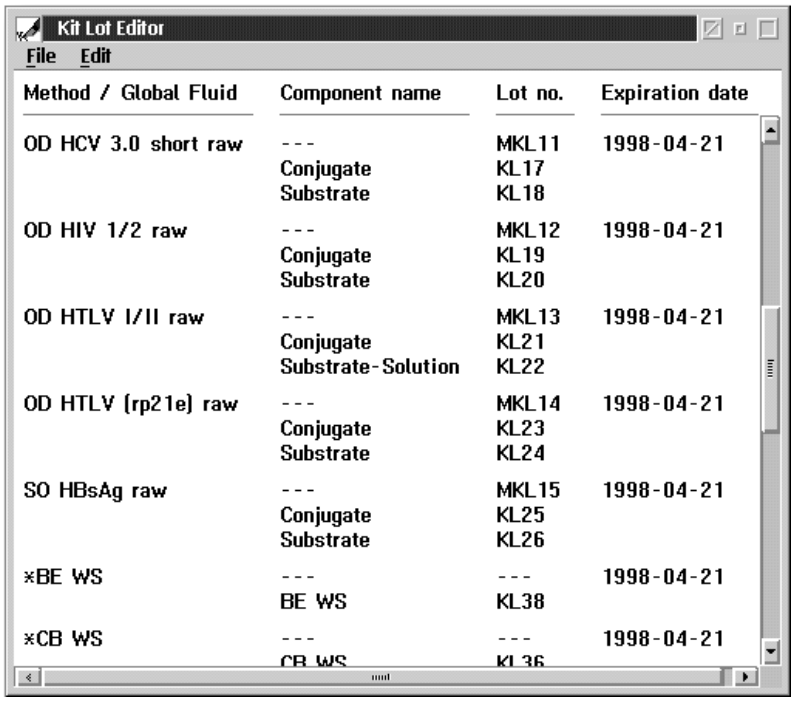


Figure 11.1 The Kit Lot Editor window

- **Component name** - lists the components of the kit lot or in the case of a global fluid the fluid name.
- **Lot no.** - lists the lot numbers for, in the case of a method, the master lot number then the component lot number or in the case of a global fluid the fluids lot number.

Expiration date - lists the defined date when the kit lot will be unusable by the ML F.A.M.E..

11.2.1 Menu Choices

- **File Menu**
  - **Save** - stores any changes made to the kit lot file to the path defined in the **Device Presettings** dialog box.
  - **Print** - prints the contents of the **Kit Lot Editor** on the OS/2 default printer.
  - **Close** - shuts down the **Kit Lot Editor**.

❒ **Edit Menu**

- ❍ **Insert Kit Lot** - allows the manual definition of kit lots and their components (see Cook Book Section - Table 4.1.3.1 - on page 44)
- ❍ **Insert Global Fluid** - allows the manual definition of the kit lot of global fluids (see Cook Book Section - Table 4.1.3.1 - on page 44)
- ❍ **Change** - allows the ML F.A.M.E. operator to edit a kit lot and its components.
- ❍ **Delete** - removes the selected kit lot from the kit lot file.

11.3 Work List Manager

A work list is a list of stack types and their earliest expected loading times. These loading times can be specified in two ways: time of day mode (i.e. an absolute time of the day and a day offset as per the time set in the ML F.A.M.E. workstation) or the delay to the previous stack loading time (i.e. an amount of time relative to the previous stack types loading time).

As work lists consist of stack types, therefore, it is not possible to define work lists if no stack types exist on the ML F.A.M.E. database.

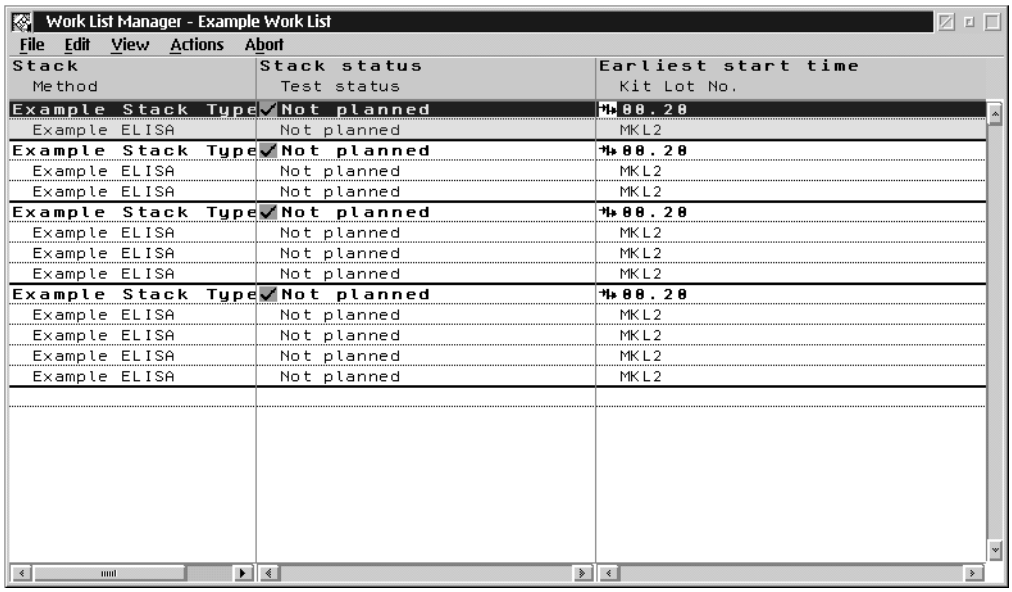


Figure 11.2 Work List Manager

To access the **Work List Manager** select the **Work List Manager** menu choice from the **Work** pull-down menu.

For a step-by-step guide to working with stack types, work lists and fluids see Cook Book Section - 4 on page 41.

11.3.1 Menu Choices

❒ **File Menu**

- ❍ **New** - allows the ML F.A.M.E. operator to create a new work list.
- ❍ **Open** - opens an existing work list.
- ❍ **Delete** - deletes an existing work list.
- ❍ **Save** - saves the current work list.
- ❍ **Save As** - saves the current work list under a new name.
- ❍ **Comment** - attaches a comment to the current work list.
- ❍ **Print** - prints the contents of the current work list on the OS/2 default printer.
- ❍ **Close** - shuts down the **Work List** Manager.

❒ **Edit Menu** (for further information on the operations of these commands see Cook Book Section - 4.2.1 on page 43).

- ❍ **Insert Stack** - displays a dialog box allowing the ML F.A.M.E. operator to choose a pre-defined Stack to include above the highlighted line in the current work list.
- ❍ **Delete Stack** - deletes the selected Stack from the current work list.
- ❍ **Set Earliest Start Time** - allows the ML F.A.M.E. operator to specify the method of defining the starting time of a work list and set the time properties.
- ❍ **Change Kit Lot** - allows the ML F.A.M.E. operator to specify the kit lot to be used by the selected method within the current work list.

❒ **View Menu**

- ❍ **View Plan** - allows the ML F.A.M.E. operator to switch to the **Plan** window (also use the **F7** keyboard key).

❒ **Actions Menu**

- ❍ **Schedule** - the schedule option will analysis the stacks and their methods in the current work list and optimize the processing order, within the stacks, returning an action list viewed with the **Plan** window.
- ❍ **Un-schedule** - will sequentially un-schedule stacks from the selected stack down.

❒ **Abort Menu**

- ❍ **Selected Test** - (after scheduling) cancels the processing of the selected test.
- ❍ **Entire Run** - (after scheduling) cancels the processing of the entire work list.

When a stack type is inserted into the work list, the following defaults are applied:

- ❒ **Earliest Start Time For The Stack**. Initially, the default start time of a stack is set to the actual time of day +20 minutes. If an earliest start time has been previously defined, it is used as default for each inserted stack.

NOTE
Kit lot changes are only allowed before scheduling is started. An Error Message will inform the ML F.A.M.E. operator if changes of the kit lots are not allowed.

- ❒ **Kit Lot**. If one kit lot has been assigned to the methods of the stack, this kit lot is used as the default. If several kit lots are assigned for a method, the operator must select the individual method's kit lot. If no valid kit lot has been assigned, the kit lot field (for the method) in the **Work List** window remains empty.

A stack type name preceded with '*' indicates that a method associated with that stack type is unchecked. Work lists containing these stack types **cannot** be executed.

11.3.2 Scheduling a Work List

When the work list definition has been completed it is then possible to create a schedule of events.

For a step-by-step guide to scheduling a work list see Cook Book Section - 4.1.4 on page 45.

During the calculation, a progress indicator will display the status of the calculation. If the scheduling was successful, the resulting plan is displayed in the **Plan** Window, which becomes the active window after successful scheduling.

It is also possible to open existing work lists using the **Open...** menu choice in the **File** pull-down menu and then start the scheduling process as described above.

The scheduler will calculate different plate stay times, however, the plate hold time defined in the method will never be exceeded. The scheduler will organise the plate order to minimize the plate stay time on any stack.

11.4 The Plan Window

The **Plan** window is a graphical representation of a scheduled work list. It displays information about the run and operator interactions, etc. The **Plan** window is displayed whenever the scheduling of a work list was successful.

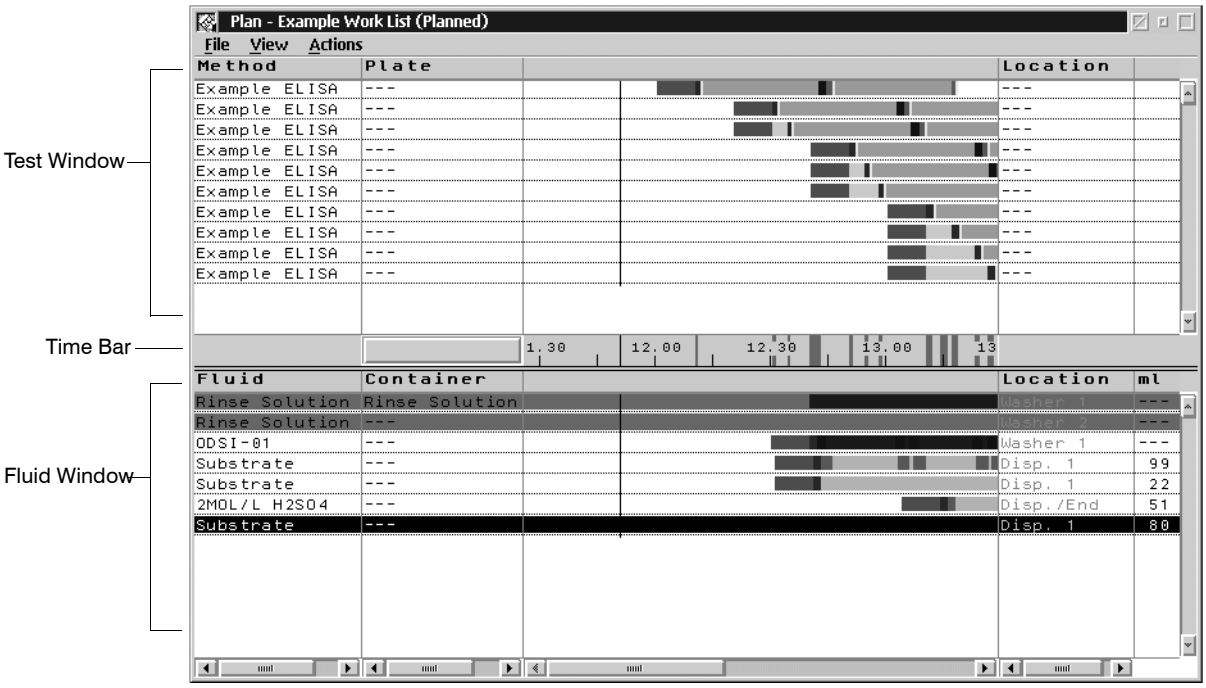

Test Window
Time Bar
Fluid Window
Plan - Example Work List (Planned)
File View Actions
Method Plate Location
Example ELISA --- ---
1.30 12.00 12.30 13.00 13
Fluid Container Location ml
Rinse Solution Rinse Solution Washer 1 ---
ODSI-01 --- Washer 1 ---
Substrate --- Disp. 1 99
Substrate --- Disp. 1 22
2MOL/L H2SO4 --- Disp./End 51
Substrate --- Disp. 1 80

Figure 11.3 Plan window

The **Plan** window is separated into three sections (rows) as follows:

- ❒ The upper part of the **Plan** window is the **Test** window.
- ❒ The bar across the middle is the **Time** bar.
- ❒ The lower part is the **Fluid** window.

11.4.1 Menu Choices

NOTE
All times referred to in the printed action list are not accurate until the work run is started.

- ❒ **File Menu**
  - ❍ **Print** - prints an action list on the OS/2 default printer.
  - ❍ **Close** - shuts down the **Plan** Window (the ML F.A.M.E. operator is prompted that this action will destroy the schedule).
- ❒ **View Menu**
  - ❍ **Details** - gives information on the selected element of the plan (i.e. if a fluid is selected information is displayed about that fluid).
  - ❍ **Current Time** - returns the window to the current time line.

- ❍ **Work List** - switches to the **Work List Manager**.

❒ **Actions Menu**

- ❍ **Assign Fluid** - allows the ML F.A.M.E. operator to assign a fluids position and associated barcode.
- ❍ **Start Run** - initiates processing of current work list's plan.
- ❍ **Edit Plate** - allows the ML F.A.M.E. operator to access a plate's sample barcode information after the plate has been loaded and accepted.

NOTE
This option is only available if the Plate Access On installation option was selected.

For further information and a step by step guide to working with the above functions see Cook Book Section - 4.1.5 on page 49.

11.4.2 Test Window

The **Test** window provides a real-time view of the processing steps for the various tests in the work list in the order arranged by the *Scheduler*.

Test Information is displayed in columns as follows:-

❒ **Method** - displays the method used by the test.

❒ **Plate Barcode** - for plates that have been loaded onto the instrument, i.e. whose barcode has been identified.

❒ **Test Action** - graphically displays the status of each test. Different colors represent various ML F.A.M.E. operator and ML F.A.M.E. actions. If an individual test is aborted the action sections for the test will appear in grey in the graphical display.

❒ The current time is indicated by a vertical line through the **Plan** window.

❒ **Location** - The plate location, i.e. in which module.

11.4.3 Time Bar

The **Time Bar** is located between the **Test** window and the **Fluid** window. It indicates the current time line using a line across the **Plan** window.

A status button in the **Time Bar** gives the ML F.A.M.E. operator a warning when a problem exists with one or more tests after scheduling. The status button is gray under normal conditions but will turn red when a test within a stack could not be scheduled. The ML F.A.M.E. operator must then select this button to confirm recognition of the problem.

The **Time Bar** is marked with vertical strips of magenta indicating a ML F.A.M.E. operator action at that time segment.

11.4.4 Fluid Window

The fluids necessary for the plan's processing are listed with the following information:

- **Fluid Name** - each individually loaded fluid is displayed on one line, (exception:- multiple loadings of an identical wash fluid are combined on one line).
- **Container Barcode** - for reagent barcodes that have been loaded onto the instrument, i.e. whose barcode has been identified**.**
- **Fluid Action** - graphically displays the status of each fluid. Different colors represent various ML F.A.M.E. operator and ML F.A.M.E. actions.
- A schematic plan of the test steps, in which the fluid is used; this includes preparation times and loading times.
- **Container Location** - the container location, i.e. in which module.
- **Container Volume** - for reagent containers only; initially, the calculated volume is displayed and after the first dispensing from the reagent container, the volume required for the next steps.

11.4.5 Changing a Work List

The scheduling of a work list may not meet all requirements or the user may want to add or delete certain stack types from the work list prior to the start of the run, for information on work lists see Cook Book Section - 4.1.4 on page 45.

11.4.6 Test Processing Statuses

Once a work list has been scheduled, i.e. after a plan exists, the statuses of the stacks and test change.

The following tables provide an overview of the statuses of the stacks and tests in the work list.

Table 11.4.6.1- Test Processing Statuses

Processing Status	Description
Running	The processing of this test has already started, but not yet finished.
Processed	Successfully processed test.
Aborting	An immediate abort of this test was started, the abort is not yet been processed.
Aborted	This test was aborted during processing.
Not loaded	This test was expected but was not loaded (less plates than expected in the stack).
Kit lot not assigned	A valid kit lot has not been assigned to the method.
Kit lot invalid	Test cannot be processed since no valid kit lot is defined.
Method invalid	Method is not checked, i.e. method was newly created or edited without method check.
No resource	Test cannot be processed since not all required resources are available (e.g. photometer filter missing, defined incubator temperature not available, etc.).
Non-processable	Scheduling did not find a solution for this test. Stack was reduced by this test.

Table 11.4.6.2 - Stack Processing Statuses

Processing Status	Description
Not planned	This stack has at least one test with the processing status *Not planned.*
Planned	No test of this stack is *Not planned* or *Running*, at least one test of the stack is *Planned*.
Running	At least one test of this stack is *Running* or *Aborting*.

Table 11.4.6.2 - Stack Processing Statuses

Processing Status	Description
Processed	All tests of this stack are *Processed*, *Aborted*, *Not loaded* or *Invalid*. However, not all test are allowed to be *Aborted*.
Aborted	All test of this stack are *Aborted*.
Non processable	All test of this stack are *Non processable*.

NOTE
An invalid status is not an actual ML F.A.M.E. state but is a general name for a test with one of the following statuses:
Kit lot invalid,
Method invalid,
No resource,
and
Non-processable.

When a work list is defined, i.e. all stack types are added to the work list, valid stacks and tests will have the status *Not planned*. After scheduling stacks and tests which could be scheduled will have the status *Planned*.

To change a work list prior to a scheduling process, simply use the menu options of the **Edit** pull-down menu of the **Work List** window to delete or insert stacks (see Reference Guide Section 11.4.5 on page 114).

11.5 Fluid Handling

Fluids used by the ML F.A.M.E. include:

- ❒ **Reagents**
- ❒ **Wash Fluids**
- ❒ **Rinse Fluids**
- ❒ **Maintenance Fluids**
- ❒ **Check Fluids**

ATTENTION
If a method definition is not complete and/or the kit lot and global component registration is missing, it is not possible to process these methods.

Certain information for the fluids must be present in order to make a method processable within a run. These are:

- ❒ **Fluid definition**. All relevant fluids are defined within the corresponding method of the ML F.A.M.E. database. For each method, either method-specific or global components have been specified.
- ❒ **Kit lot and component lot information**. The kit lot information contains the registration of the method's kit lot; these contain the kit lot numbers of method-specific components and additionally of all global components.

There are two ways to handle fluids while processing a run:

- ❒ Reservation of fluid container barcodes for the different fluids prior to the run using the Assignment Editor.
- ❒ Assignment of fluid container barcodes during the run (during fluid loading steps).

11.6 Assignment Editor

The assignment editor is accessible via the **Work** pull-down menu in the **Main** ML F.A.M.E. window. This editor is used to reserve container barcodes for predefined methods and modules.

11.6.1 Fluid Container Barcode Reservation

It is possible to define several container barcodes for each fluid, however, each container barcode must be unique, i.e. it is not possible to use identical container barcode assignments for several different fluids.

NOTE
Assigning several container barcodes for each fluid will make the daily operation easier.

In a similar fashion, the user can remove previously assigned container barcodes from the assignment table, e.g. when no longer using a particular method.

11.6.2 Reserved Bar Codes

There are 4 barcodes that are reserved by the ML F.A.M.E. software for service containers, these are:

Reagent Containers

- ❒ **REAGENT 46.00**
- ❒ **REAGENT 47.00**
- ❒ **REAGENT 48.00**
- ❒ **--- (i.e. three minus signs/dashes)**

Wash Container Slots

- ❒ **Cont. 1, Cont. 2, to Cont. 8**

Rinse Fluid

- ❒ **Rinse Sol. 1**
- ❒ **Rinse Sol. 2**

Reserved barcodes are not displayed in the **Assignment** editor and cannot be changed.

11.7 Starting a Run

After fluid assignment, work list definition (or loading) and scheduling, the **Plan** window will be the active window. If any of the fluids used in the run are not included in the fluid assignment table, they must be assigned container barcodes prior to starting or during the run.

This is done via the **Actions**/**Assign fluids...** pull-down menu option in the **Plan** window. Here, the ML F.A.M.E. operator may overrule any definitions which have been automatically included by the scheduler from the assignment table (see Cook Book Section - Table 4.1.6.1 - on page 51).

After these definitions are complete, start the run by selecting the **Actions**/**Start run** menu option form the **Plan** window.

11.7.1 Fluid Handling - General Remarks

As mentioned earlier, fluids are defined as all reagents for dispensing operations, the wash fluids and the rinse fluid. Additionally, some of the reagents may be unstable. Therefore, the fluid handling differs slightly depending on the nature of the fluids.

Some general principles apply to all fluids:

- ❒ Fluids usually have a preparation time defined in the method; this preparation time is taken into account during the scheduling and is also displayed in the **Fluid** window of the **Plan** window.
- ❒ For each fluid, a loading step is planned, i.e. a time span is reserved in the plan to load fluids without any negative consequences on the run (i.e. delays of other steps, etc.). As many fluid loading steps are combined in one loading step as possible. Fluid loading steps are also displayed in the **Fluid** window.
- ❒ The loading of fluids may be postponed if the operator has insufficient time during the loading step or wants to postpone the fluid loading for whatever reason. Postponed fluid loadings are also displayed in the **Fluid** window.
- ❒ Any barcode on a fluid container must be unique within a run.
- ❒ Some fluids must be verified, i.e. the component kit lot of the fluid must be checked against the registered kit lot file to see whether it matches or not. This check must be done prior to the use of this fluid. In the case of unstable fluids this verification must be carried out during the preparation time or at loading. The definition, whether a fluid must be verified or not, is contained in the method definition.
- ❒ For the fluid's verification, a hand-held barcode scanner connected in parallel with the computer's keyboard can be used. Fluid verification follows a double-blind entry principle (see Cook Book Section - Table 4.1.7.1 - on page 52).

NOTE
Do not load unstable reagents into the reagent drawers until requested by an Operator Action dialog box.

NOTE
When a fluid is defined with the Verify Fluid option on, it is critical to the schedule that when the ML F.A.M.E. operator is prompted to perform this verification it is carried out as soon and as quickly as possible.

NOTE
While unneeded fluids may be removed from the ML F.A.M.E. when prompted by the ML F.A.M.E. software, this may not be done if a dispensing step is scheduled for the next 5 minutes.

ATTENTION
It is important that the ML F.A.M.E. operators ensure that correct fluids are placed in the correct, labeled, container.

ATTENTION
When pouring reagents into the reagent containers, ensure that there is no foam on the surface of the liquid.

- ❒ All fluids must be correlated, i.e. in addition to the fluid container barcode check and the component lot verification, the container must be connected to a certain position on the instrument, either automatically in a certain reagent container carousel position or manually in a defined wash channel position.

When preparing the reagents, observe the following points:

- ❒ Ensure that the conductive insert is in place in the bottom of the reagent container.
- ❒ Attach the correct barcode label to the reagent container, i.e. the barcode assigned to the reagent.
- ❒ Place a disposable syringe in the “parked” position of the reagent container.
- ❒ Before inserting the reagent container into the reagent container carousel, put the cap in the “service” position (i.e. in its recess) and check that it is firmly seated.

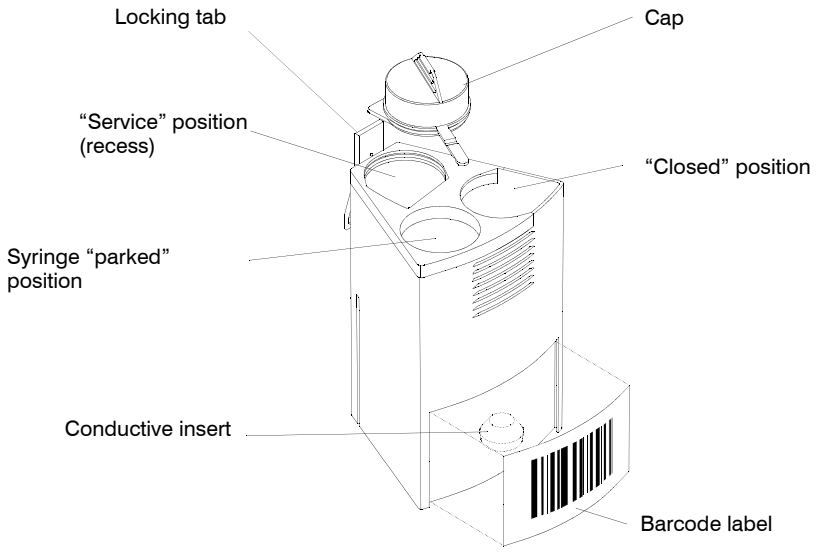


Figure 11.4 Reagent Container: Definition of Terms

11.7.2 Inserting the Reagent Containers into the Carousel

Insert the prepared reagent containers into the reagent container carousel.

Note the two grooves in the reagent container which slide into the two tongues in each segment of the reagent container carousel. The reagent container is locked in place by the locking tab which clicks into the slot in the carousel.

11.7.3 Using Reagent Container Carousels

NOTE
The reagent drawers should only be opened by their handles. The handle contains a switch which tells the ML F.A.M.E. software that the drawer is open.

ATTENTION
Make sure to put the reagent container in the correct reagent drawer as specified in the Fluid Loading dialog box.
Ensure that all reagent container caps are pressed firmly into their recesses (caps in open position) and that the syringe plungers are fully down so that they do not foul on the module chassis when the drawer is closed.

To insert a reagent container carousel in a drawer, open the reagent drawer smoothly by the handle.

Hold the reagent container carousel by the knob in the centre and slide it onto the spindle in the reagent drawer.

Rotate the reagent container carousel by the knob until it drops and locks into place.

Close the reagent drawer gently. Slamming the drawer shut may cause reagent spillage.

Do not open a drawer and remove or add reagent containers while the dispenser is active or while the reagent container carousel is rotating.

11.7.4 Fluid Handling for Stable Reagents

NOTE
Stable fluids may be loaded prior to their preparation time, during their preparation time, during a loading step or after the loading step. For safety reasons, it is recommended to load fluids only during their loading time. The main reason is that for all other times, no instrument resources are reserved for fluid loading, i.e. the fluid's loading may interfere with other processing steps and may cause delays in the run.

In the schedule, the loading step is included and planned to ensure a safe execution of the fluid loading. All fluids that are planned to be loaded at this time, a **Loading** dialog box is displayed.

The effect of pressing the **Ignore** button is that the loading of the fluids which have not been assigned by the operator, will be postponed.

When the **Assign...** push button is pressed, the **Assignment** dialog box for the selected fluid is displayed. The reagent container barcode has to be entered in the **Assign Container Barcode** entry field . If container barcodes have been reserved for this reagent in the fluid assignment table, it is displayed in this field (or all, if several container barcodes have been reserved); depending on the nature of the reagent definition, one of three dialog boxes is then displayed.

- ❒ **Fluid assignment definition - verification flag OFF**
  A unique component lot number must be present.

- ❒ **Fluid assignment definition - verification flag ON**.
  For all reagents of this type, not only the reagent container barcode, but also the component kit lot number(s) for the reagent (or its sub-components) must be entered.
  In the verification entry fields, the component lot number(s) must be entered as a double-blind entry (see Cook Book Section - Table 4.1.7.1 - on page 52). Only if both entries are completely identical, the entry is accepted. The entry can be made either via keyboard or by using a hand-held barcode scanner.

ATTENTION
Verification flag ON is only processable with Installation mode „Active Kit Lot Check".

ATTENTION
The definitions in the fluid Assignment dialog boxes must be complete in order to leave the dialog box. Any discrepancies, e.g. incorrect double-blind (see Cook Book Section - Table 4.1.7.1 - on page 52) entries, etc. will result in error messages and the dialog box remains open.

❒ **Fluid assignment - verification flag OFF and non-unique component lot numbers**.

Finally, for those reagents which do not require a verification (verification flag OFF), but for which several component numbers exist. The drop-down lists in the **Selected Component Lot No.** field lists all registered component lot numbers of this reagent. The ML F.A.M.E. operator must select the one that you are actually using.

11.7.5 Loading of Unstable Reagents

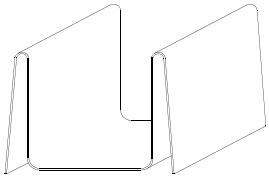
ATTENTION
The stability time of unstable reagents starts as soon as the corresponding loading step has been started by the system. Any unstable reagent must be at least stable until the start of the dispensing step.

Reagents which have been defined within the method as unstable, can only be loaded during their preparation and/or loading time.

The above procedures for assignment and verification of stable reagents can also be preformed for unstable reagents, however this must be started after the reagents' preparation time has begun.

11.7.6 Loading of Wash Solutions

General Remarks



Wash Container Stand

ATTENTION
It is possible some liquid may leak through the thread of the cap due to the vent.

❒ Prepare the wash and rinse fluids at the times specified in the **Plan** window.

❒ When decanting wash/rinse fluid into a wash fluid container, place the wash fluid container on the wash container stand (supplied with instrument). This allows it to be placed on its side with the cap facing upwards.

❒ Unscrew the wash container cap.

❒ Fill the wash container with the wash/rinse fluid (max. 3 l).

❒ Replace the wash container cap. Make sure it is screwed on tight.

❒ Slide the wash container into the appropriate position in the container stack.

- ❍ Wash containers should be clearly labelled in order to distinguish between wash solutions (both in and outside the instrument).
- ❍ Never load a wash fluid container when the orange status light is lit (see Figure 11.5).
- ❍ Green light = wash channel ready.
- ❍ Orange light = wash channel in use.
- ❍ Flashing Green light = container empty.

To connect up the wash fluid container, pull out the fluid connector from the rinse position (vertical), turn, and push into the wash container outlet.

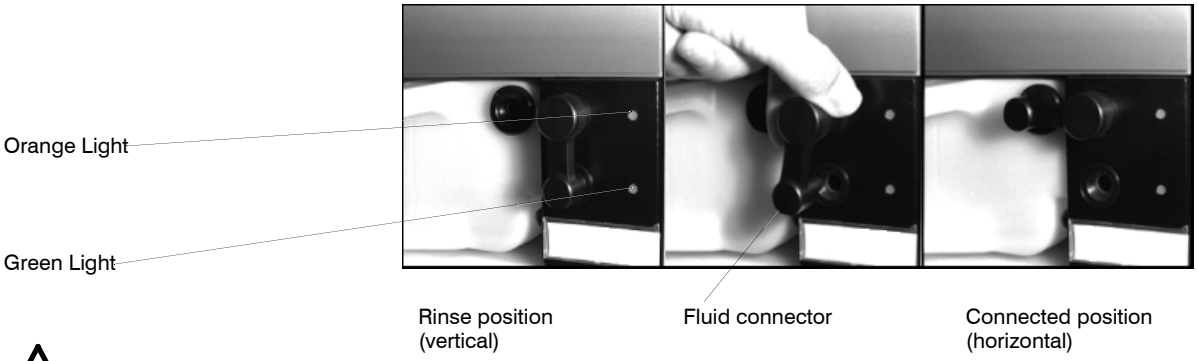


Figure 11.5 Connecting Wash Fluid Container

ATTENTION
Never leave fluid connectors unconnected. They must be put in either the wash position or the rinse position.

After a wash solution has been loaded into the instrument, the **Correlation** dialog box will automatically appear, in which a wash container barcode has to be assigned to the wash channel barcode.

11.7.6.1 Wash Solution Loading Dialog Box

ATTENTION
If a Wash Fluid Almost Empty Warning dialog box or an Insufficient Liquid error dialog box appears, the appropriate wash fluid container should be exchanged/refilled immediately. The dialog box will then automatically disappear.

NOTE
The volume of the wash solution is monitored by the system but only a warning is given. Thus, it remains with the operator's responsibility to ensure that there is sufficient wash solution in the wash container or a sufficient number of wash containers are loaded.

The Loading of a wash container is requested by the system using the **Fluid Loading** dialog box. The dialog box is closed by either finishing the last necessary identification or by pressing the **Ignore** button to postpone the loading.

If all wash containers have not been loaded, the dialog box remains open, i.e. the ML F.A.M.E. operator must manually close the dialog box.

Whenever a wash container is loaded, i.e. when the wash connector switch is moved from the vertical position to the horizontal position, the wash **Container Correlation** dialog box is displayed. In this dialog box, the container barcode and the wash channel barcode must be entered by the ML F.A.M.E. operator. Both entry fields follow the double-blind entry principle (see Cook Book Section - Table 4.1.7.1 - on page 52) and can be defined either via keyboard or hand-held barcode scanner.

Identical wash solutions can be loaded to different channels of the wash container stack. The different containers must have the identical container barcode in order to be detected as identical wash fluids. If several identical wash fluid containers are present, the system ensures that the one that was loaded at the earliest time is initially used.

11.7.7 Plate Preparation and Sample Pipetting Information

Sample pipetting into the wells of a plate is an external task and cannot be controlled by the system. However, assistance is provided to the operator in form of the definition of the plate preparation time in the method definition. This time is taken into account during scheduling and is also displayed in the **Plan** window to inform the ML F.A.M.E. operator that a plate's pipetting is due.

Since the system cannot monitor the sample pipetting procedure, it does not know which well of a plate was pipetted. For this reason, additional sample pipetting information must be provided to the system at the time a plate is loaded onto the instrument. This information must be provided in a specific form. The directory into which this file is written can be set by using the **Device Presettings** menu choice from the **Services** menu in the **Main** ML F.A.M.E. window.

11.7.8 Plate Loading

NOTE

It is possible to load stacks prior to the expected loading time, but only if the green light is on, see Figure 11.6. If the stack type consists of only one plate, the plate may be placed directly on the entry platform without using the entry stack.

Place the prepared plates on the entry stack to give the required stack type as specified in the action list. Position the plates such that well A1 is at the outer left corner and butt the rear edge against the back of the entry stack.

Place the entry stack on the entry platform when requested by the ML F.A.M.E. software. Ensure that it sits flat and inside the lips of the platform.

Press the load button to activate the loading sequence.

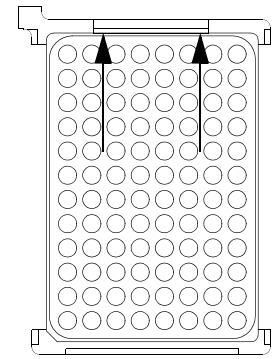
The barcodes will be read, verified and the plates systematically loaded onto the transport system of the instrument.

ATTENTION

It is important that plates stay in the same order on the entry stack *after* plate barcode identification.

If placing plates directly on the entry platform (i.e. without the entry stack), ensure that the rear edge of the plate butt against the ledge at the back of the entry platform.

It is also possible to load a stack that does not containing all of the defined plates for this stack, however, it must contain the next plate required in the plan.



When not using entry stack, rear edge of plate must butt against ledge at back of entry platform

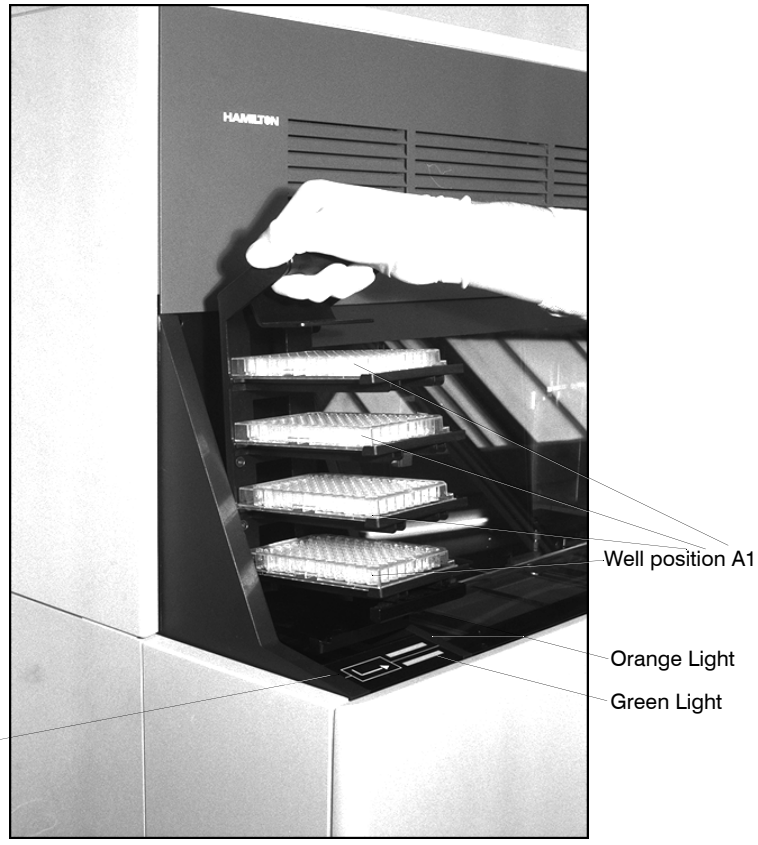


Figure 11.6 Entry Stack Loading

Entry Lift Signal Lights

The green and orange signal lights next to the entry lift have the following meanings:

Green Light

When the green light is on, a plate/stack may be placed on the entry platform.

Orange Light

When the orange light is on, a plate/stack may not be placed on the entry platform.

A flashing orange light indicates that a plate/stack is in the process of being loaded into the instrument, i.e. the entry lift is moving or will soon move. In general, a **Stack Loading** dialog box is displayed whenever plates have not been loaded at the required time or will be moved soon. The dialog box graphically displays the stack and all plates according to the stack type definition.

ATTENTION
Do not swap plates on the entry stack after loading.

This dialog box is either closed by loading the required stack onto the instrument and pressing the **Load** button on the instrument or by selecting the **Abort plate** button. Pressing the **Abort plate** button will result in the aborting of the next plate required by the instrument.

Once a plate has been loaded to the instrument, several checks are executed which ensure that everything is alright with the loaded plate. These checks are:

- **Plate detection**. The number of plates on the entry stack is detected to check whether any plate has been loaded. If no plate has been found, the entry stack moves back to the uppermost position.

- **Plate identification and plate barcode check.** The plate barcode of each plate detected on the stack is read. If no or unreadable plate barcodes are detected, the operator has the opportunity to enter the plate barcodes as part of the error handling. The operator definition of the plate barcode follows the double-blind entry principle (see Cook Book Section - Table 4.1.7.1 - on page 52).

- **Plate integrity check**. At the start of the plates planned loading time (displayed as a dark red block in the **Plan** window) an initial check is made to find the pipetting information file.
  If no pipetting information file is found, an error message is displayed and the plate is not accepted (if the ML F.A.M.E. software has been installed with the **Plate Access On** option the ML F.A.M.E. operator will get the option to continue processing without pipetting information).
  The barcode on the plate must be unique, i.e. the plate's barcode must not already exist on the ML F.A.M.E. database. If a non-unique plate barcode is detected, the operator must repeat the complete loading sequence without the plate with the not unique barcode. Plates containing non-unique barcodes will never be accepted for loading.
  If no matching plate barcode is detected, an error message is displayed to the operator (i.e. if the plate's barcode does not match with the required plate's barcode mask defined in the method definition).

NOTE
Kit lot documentation mode:
The defined kit lot from the kit lot file and the used kit lot, if available, will be documented but not compared.

- **Kit lot check**. The expected kit lots are defined for each plate in the work list. The used kit lot number is either part of the plate barcode (see Reference Guide Section 10.2.1 on page 86), which has the higher priority, or is part of the pipetting information. When the ML F.A.M.E. software has been installed with the Active Kit Lot Check mode, then both the expected and the used kit lot numbers must completely match to accept a plate's loading.

- **Reading of time stamp of barcode file**. The span between this time stamp and the defined first processing step (plate stay time) must be less than the plate hold time (as defined in the method definition); else, the plate will be aborted at the time when the 'first processing step' of the method is due. The oldest plate of a similar method in a stack is given priority.

- **Plate assignment**. Once all the above have been completed a test number is created, the plates barcode is registered and displayed in the **Plan** window, and a loading time assigned.

❒ **Well identification**. The pipetting information file is inspected when the plate is loaded. The inspection of the pipetting information file can result in the detection of errors occurring during the sample pipetting or a mismatch of the well definitions between the pipetting information file and the method definition. In these cases and if an incomplete plate is detected, an error message is displayed explaining the discrepancies.

11.8 Changing a Run

NOTE
It is not possible to change a plan when it is processed. Any difficulties experienced during the run, i.e. delays of the processing of test steps, are brought to the attention of the operator, but a rescheduling of a running work list will never be carried out by the system automatically. This avoids any situations where the operator is not aware of any changes of the plan.

It is generally possible to change a run during its processing. There are three possibilities as follows:

❒ **Abort Test**

❒ **Un-scheduling of stacks**

❒ **Re-scheduling of a work list**

To change a run during processing, the ML F.A.M.E. *operator must switch from the* **Plan** *window to the* **Work List** *window.*

11.8.1 Un-schedule

ATTENTION
The **Un-schedule** option is only applicable to a stack which has the status ‘planned’. stack types which are ‘not planned’, ‘processed’, ‘aborted’ or ‘non-processable’ can only be deleted from the work list.

Select the stack type to be changed or deleted or at which position you may wish to insert a stack and select the **Un-schedule** menu choice from the **Actions** menu. All stacks including the selected and the following stacks in the work list are then removed from the plan.

After applying the **Un-schedule** option in the **Work List** window and making the changes in the run by using the options of the **Edit** pull-down menu in the **Work List** window, schedule the altered work list again by selecting the **Schedule** option from the **Action** menu.

Whenever the **Un-schedule** option is applied to a running work list, the **Plan** window is accordingly updated, i.e. all plates and fluids which are no longer used in the changed work list or are not yet used, i.e., their preparation time has not started, are removed from the plan. The same is true after the schedule of an altered work list.

11.8.2 Reschedule

Rescheduling a running plan is basically the procedure described in the section above. During the processing of a run, delays may occur, either based on delayed operator activities or any problems encountered during the run that delayed certain process steps.

Whenever the system detects that the run might be endangered, it forwards information to the operator and suggests a re-scheduling of the work list.

Recalculation of reagent volume and containers during reschedule

- ❒ The loaded reagent volumes will be taken into consideration, e.g., the unused reagent from aborted plates.
- ❒ The above is also true for reagents with already started preparation times, whether loaded or not.
- ❒ It is not possible to refill containers. If more reagent is required new containers must be used.

11.9 Aborting a Plate or Run

11.9.1 Aborting Plate

Plates can either be aborted by the operator or by the system. Any plate that is aborted by the system, either as a consequence of a delayed operator response, the violation of any of the check procedures (e.g. during plate loading, violation of any of the method-defined run steps, etc.) or due to a malfunction of the system (i.e. that certain vital instrument functions are locked due to an error), is automatically aborted and the operator is informed about this.

The operator can also initiate aborting a test by selecting the **Abort**/**Abort Test...** option in the **Plan** window. Any operator-initiated test abort must be confirmed and is also traces in the test trace.

The confirmation of a test abort results in the transport of the selected test to the manipulation position. During the transport, the test's run status is set to *aborting* and after removal from the manipulation position, it is set to *aborted*.

11.9.2 Aborting a Run

The operator can decide to abort a complete run, i.e. finish the work list before it is completed by selecting the **Abort**/**Abort Run** option from the **Plan** window. Aborting a run must be confirmed by the operator and results in the removal of all plates from the instrument and in finishing the run.

11.10 Finishing a Run

A run is finished when the processing of all plates in the work list is finished. Then, close the **Plan** window by selecting the **Close** option from the **File** pull-down menu in the **Plan** window.

This returns focus to the **Work List** window, close the work list manager that has been scheduled and processed.

A new run is started by the ML F.A.M.E. operator opening or creating a new work list.

After the test's processing, depending on the documentation jobs defined for the methods used, the test results must either be realesed manually in the **Test Results** window or it if defined this will be done automatically. Test results may be viewed in the **Test Results** window.

Chapter 12 Test Results & ML F.A.M.E. Traces

Table of Contents

12.1 - Overview....130
12.1.1 - The Test Results Window....131
12.1.2 - Well Flag....132
12.1.3 - Photometer Overflow and Underflow....132
12.2 - Managing Test Data....133
12.2.1 - Releasing Test Documentation....133
12.2.2 - Documenting a Batch of Tests....133
12.2.3 - Storing Results....133
12.2.4 - Archiving Test Data....134
12.2.5 - The ASTM File....134
12.3 - Trace Reports....135
12.3.1 - Trace Priority....135
12.3.2 - System Trace....135
12.3.3 - Test Trace....136
12.3.4 - Well Trace....136

12.1 Overview

Once a test has been processed by the system, all test results operations are undertaken from within the following two windows/ dialog boxes:

- ❒ **Test Results** window (see Cook Book Section - 5.1.1 on page 56). This window displays all tests that have been processed and therefore have information stored in the ML F.A.M.E. database.

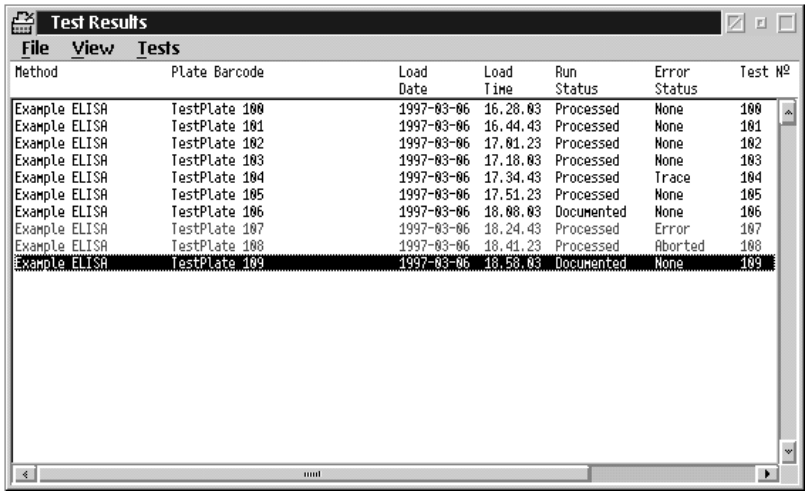

Test Results
File View Tests
Method | Plate Barcode | Load Date | Load Time | Run Status | Error Status | Test Nº
Example ELISA | TestPlate 100 | 1997-03-06 | 16.28.03 | Processed | None | 100
Example ELISA | TestPlate 101 | 1997-03-06 | 16.44.43 | Processed | None | 101
Example ELISA | TestPlate 102 | 1997-03-06 | 17.01.23 | Processed | None | 102
Example ELISA | TestPlate 103 | 1997-03-06 | 17.18.03 | Processed | None | 103
Example ELISA | TestPlate 104 | 1997-03-06 | 17.34.43 | Processed | Trace | 104
Example ELISA | TestPlate 105 | 1997-03-06 | 17.51.23 | Processed | None | 105
Example ELISA | TestPlate 106 | 1997-03-06 | 18.08.03 | Documented | None | 106
Example ELISA | TestPlate 107 | 1997-03-06 | 18.24.43 | Processed | Error | 107
Example ELISA | TestPlate 108 | 1997-03-06 | 18.41.23 | Processed | Aborted | 108
Example ELISA | TestPlate 109 | 1997-03-06 | 18.58.03 | Documented | None | 109

Figure 12.1 Test Results Window

- ❒ **Test Results Report** dialog box (see Cook Book Section - 5.1.2 on page 58) displays the results of an individual test.

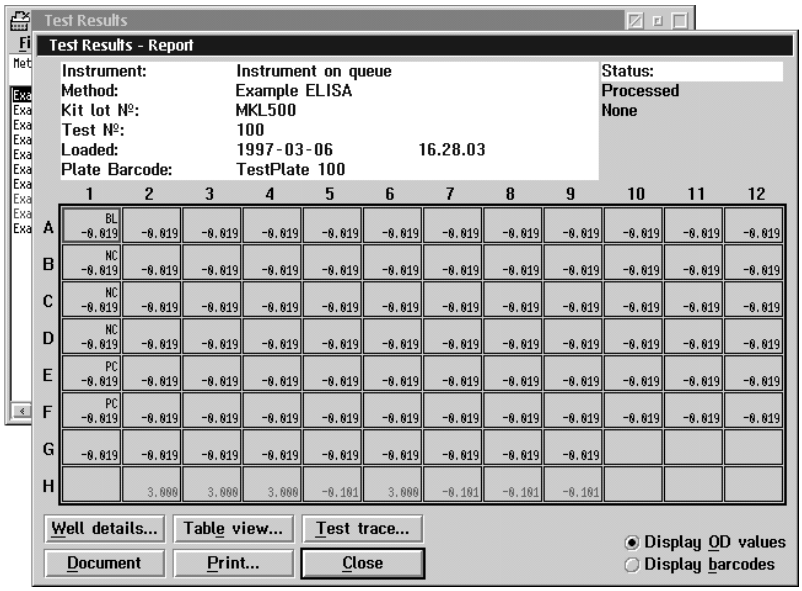


Figure 12.2 Test Results Report Dialog Box

12.1.1 The Test Results Window

The following is an explanation of the contents of the **Test Results** Window. For further information on the workings of this window, see Cook Book Section - Table 5.1.2.1 - on page 58.

The window is in a table format with the rows representing individual tests and the columns information on these tests.

- **Method** - the method used for the test.
- **Plate Barcode** - the barcode assigned to the test's plate.
- **Load Date** - recorded date of the plates entry onto the ML F.A.M.E..
- **Load Time** - recorded time of the plates entry onto the ML F.A.M.E..
- **Run Status** - can be one of the following:
  - *Processed* - indicates that the test has been processed and is awaiting the documentation.
  - *Documented* - indicates that the test has been completed in all respects, i.e. all documentation jobs have completed.
- **Error status** -indicates whether a test's processing was erroneous or not. It can have one of the following statuses:
  - *None* (empty) - this indicates that all test processing steps were completed successfully.
  - *Trace* - indicates that at least one well was marked (flagged), however, the test is still valid and its processing was finished. Further information is in the well trace.
  - *Error* - indicates that an error occurred during the test's processing which has effected either the complete plate or individual wells. The effected wells cannot be positively identified. Further information about the occurred error is included in the test trace.
  - *Aborted*. The test's processing was aborted. The reason for this is included in the test trace.

For information on how a tests status affects the tests documentation see section 12.2.1 on page 12-133.

12.1.2 Well Flag

Each well in the test result report has an associated well flag which can have one of the following statuses:

- **None** (empty) indicates that there are no entries in the well trace.
- **tr** (abbreviation for 'trace') indicates that there are errors, warnings or messages in the well trace.
- **ex** (abbreviation for 'excluded') indicates that this well is excluded. The causing error could have occurred either during sample pipetting (by using the Microlab AT/ATplus2), during processing in the instrument, or the well was manually excluded by the operator. The well trace gives more details about the cause of the exclusion.

12.1.3 Photometer Overflow and Underflow

If a photometer overflow or underflow occurs during a well measurement, the result is handled in two different ways.

- **Display of OD values:**
  - A photometer overflow is indicated by an OD value of 3.000 in the test result report display.
  - A photometer underflow is indicated by an OD value of -0.101 in the test result report display.
- **Documentation of OD values in the ASTM result file:**
  - A photometer overflow is indicated by an OD value of 9.999 in the test result report ASTM file.
  - A photometer underflow is indicated by an OD value of 8.888 in the test result report ASTM file.

12.2 Managing Test Data

12.2.1 Releasing Test Documentation

Below are listed the ways to handle the method-specific documentation of a test's results:

- **Start by user**: When the **Start documentation by the user** check box is selected the ***OSP*** operator must manually start the documentation (see Cook Book Section - Table 5.1.2.1 - on page 58).
- **Autostart**: When the **Start documentation by the user** check box is **not** checked all defined documentation jobs will be started automatically on completion of processing; unless the error status of the test is set to 'Aborted'.
- **Always start documentation** - this is a check box found in the Software Presettings dialog box. When it is selected all defined documentation jobs in all processed methods, regardless of the error status, will be started automatically on completion of processing.
  This setting overrides the 'Start by user' and 'autostart' mode.

12.2.2 Documenting a Batch of Tests

NOTE
The **Document test batch...** action will not change the test status of the selected tests.

The **Document Test Batch...** action allows one or more selected tests to be documented using a selectable documentation format and the results to be sent to a selectable device independent of the documentation definition specified in the method definition (see Cook Book Section - Table 5.1.2.1 - on page 58).

12.2.3 Storing Results

The ML F.A.M.E. software is able to keep a large amount of test data in the ML F.A.M.E. database, provided there is enough disk space. However, it is not recommended to keep more tests in the ML F.A.M.E. database than necessary as system performance will decrease.

Once test results have been documented, i.e. printed and sent to the host and archived, they should be deleted from the ML F.A.M.E. database. It is the responsibility of the ML F.A.M.E. operator to ensure that the documentation process was successful as the ML F.A.M.E. software will automatically set the status to documented regardless of possible problems such as printer failure, etc.

When 700 test results are stored in the ML F.A.M.E. database and a new set of results are generated the oldest existing results are deleted to make room in the ML F.A.M.E. database for the new one.

12.2.4 Archiving Test Data

ATTENTION
It is impossible to bring ASTM result files back into the database, i.e. only unidirectional communication with a host computer is possible.

The host connection facilities of the ML F.A.M.E. software enables archiving of test data, in ASTM format, on any accessible drive/network drive.

As a rule test archiving is performed by the host or higher system and is not a day-to-day ML F.A.M.E. operator task.

12.2.5 The ASTM File

An ASTM (American Society for Testing and Materials) file is a standard format used for host reporting. All test results from the ML F.A.M.E. are stored in this format.

The ASTM file from the ML F.A.M.E. contains;

- all test trace information (except the system trace which is not test-specific)
- the OD values
- and general test information, i.e., method used, plate barcode, kit lot information, instrument serial number, etc.

12.3 Trace Reports

A trace report gives a complete history of events which have taken place on the system. The following types of trace report are available:

- **System Trace** - tracks all important events and data throughout the entire system and includes ML F.A.M.E. operator actions, ML F.A.M.E. software functions, ML F.A.M.E. procedures and also all test trace and well trace information.
- **Test Trace** - tracks all events and data for each and every test.
- **Well Trace** - tracks only exceptional events for the wells in a test and is normally blank.

NOTE
Opening or viewing a trace window during a run is not recommended.

For information about working with the Trace window see Cook Book Section - Table 5.2.1.1 - on page 60.

12.3.1 Trace Priority

Each trace message carries one of the following priority levels:

- Level 1: Note
- Level 2: Warning
- Level 3: Error

For information about working with priority levels see Cook Book Section - Table 5.2.1.1 - on page 60.

12.3.2 System Trace

The system trace records all important events and data throughout the complete system, i.e. ML F.A.M.E. operator actions, ML F.A.M.E./ML F.A.M.E. software events and test information). It is used to record the complete process and system changes.

The system trace can be useful for identifying problems with the instrument and the user software, and also for identifying when a particular event took place.

For information about working with the **Trace** window see Cook Book Section - Table 5.2.1.1 - on page 60.

12.3.3 Test Trace

The test trace report gives a complete history of a test. The test trace can be useful for identifying problems with a test, such as at what stage a test was invalidated and why.

For information about working with the Trace window see Cook Book Section - Table 5.2.1.1 - on page 60.

12.3.4 Well Trace

The well trace report gives a complete history of each individual well in a test. The well trace can be useful for identifying persistent problems with a particular well position and hence can help point out instrument problems.

Chapter 13 ML F.A.M.E. Functions & Requirements

Table of Contents

13.1 - Overview.....138
13.2 - Services Menu.....138
13.2.1 - Instrument Status Window 138
13.2.2 - Trace 140
13.2.3 - Download.....140
13.2.4 - Device Presettings.....141
13.2.5 - Software Presettings.....142
13.2.6 - Set System Time.....145
13.3 - Access Rights.....145

13.1 Overview

This section contains information on the various functions required to perform the upkeep of the ML F.A.M.E..

13.2 Services Menu

The main access point for these functions is the **Services** menu in the **Main** ML F.A.M.E. window.

13.2.1 Instrument Status Window

The **Instrument Status** window has two main functions, the first allows the ML F.A.M.E. operator to view the current temperature of each incubator slot in the ML F.A.M.E. and the second is used to view the lock-status and to unlock any locked instrument functions.

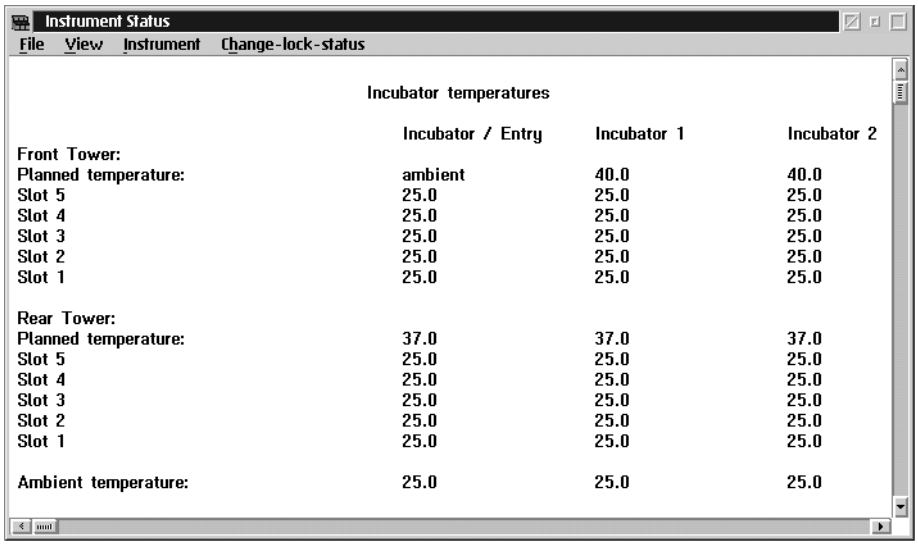

Instrument Status
File View Instrument Change-lock-status
Incubator temperatures
Incubator / Entry Incubator 1 Incubator 2
Front Tower:
Planned temperature: ambient 40.0 40.0
Slot 5 25.0 25.0 25.0
Slot 4 25.0 25.0 25.0
Slot 3 25.0 25.0 25.0
Slot 2 25.0 25.0 25.0
Slot 1 25.0 25.0 25.0
Rear Tower:
Planned temperature: 37.0 37.0 37.0
Slot 5 25.0 25.0 25.0
Slot 4 25.0 25.0 25.0
Slot 3 25.0 25.0 25.0
Slot 2 25.0 25.0 25.0
Slot 1 25.0 25.0 25.0
Ambient temperature: 25.0 25.0 25.0

Figure 13.1 The Instrument Status Window (Temperature Mode)

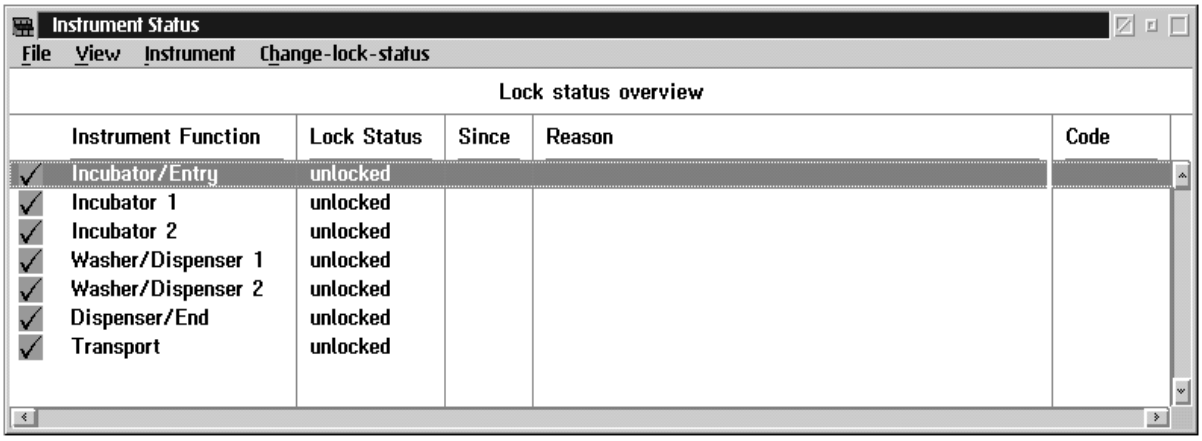


Figure 13.2 The Instrument Status Window (Lock Status Mode)

In both window modes the menu choices remain the same. These are:

- **File** Menu
  - *Close*
- **View** Menu
  - *Temperature* - Toggles the window to Temperature mode.
  - *Lock Status* - Toggles the window to Lock Status mode.
  - *Refresh Now*
- **Instrument** Menu
  - *Initialize* - Runs a full instrument initialization, connecting or reconnecting the ML F.A.M.E. software to the ML F.A.M.E..
  - *Prepare for Service* - Will disconnect the ML F.A.M.E. software from the ML F.A.M.E. allowing the user to update the ML F.A.M.E. settings without influencing with the actual instrument settings. It is also not possible to affect some settings while connected to the ML F.A.M.E.. Necessary activity prior to downloading firmware.
- **Change Lock Status** Menu (see Cook Book Section - on page 64).

  Each instrument function available with the current configuration is displayed with their current lock status.

Within each function a number of subsidiary functions are accessible, i.e. the Incubator/Entry instrument function contains:

Module Transport,
Front Tower (with 5 Slots),
Rear Tower (with 5 Slots),
Plate Barcode Reader,
and the Entry Lift.

These subsidiary functions can be individually locked or unlocked by the system or by the ML F.A.M.E. operator, independently of the others.

An icon placed before each function name gives at a glance information, i.e.

- Status normal

- Subsidiary function locked

- Entire function locked

13.2.2 Trace

For information on ML F.A.M.E. Traces see Reference Guide Section 12.3 on page 135

13.2.3 Download

Download is used for updating the ML F.A.M.E. firmware and is not a general ML F.A.M.E. operator action.

13.2.4 Device Presettings

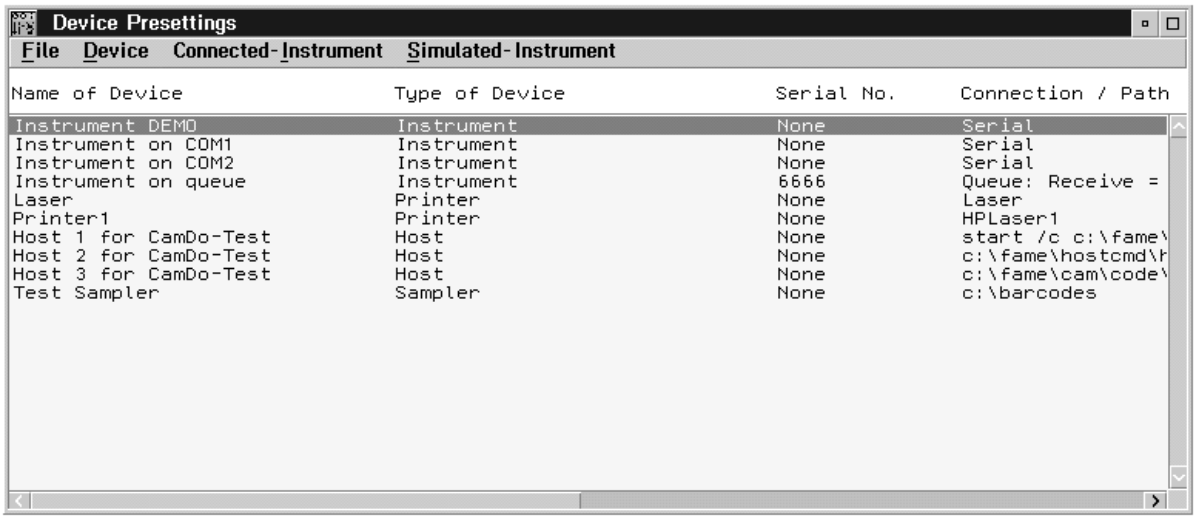

Device Presettings
File Device Connected-Instrument Simulated-Instrument
Name of Device
Type of Device
Serial No.
Connection / Path
Instrument DEMO Instrument None Serial
Instrument on COM1 Instrument None Serial
Instrument on COM2 Instrument None Serial
Instrument on queue Instrument 6666 Queue: Receive =
Laser Printer None Laser
Printer1 Printer None HPLaser1
Host 1 for CamDo-Test Host None start /c c:\fame\
Host 2 for CamDo-Test Host None c:\fame\hostcmd\h
Host 3 for CamDo-Test Host None c:\fame\cam\code\
Test Sampler Sampler None c:\barcodes

Figure 13.3 The Device Presettings window

This window allows ML F.A.M.E. operators, with sufficient access rights (see Reference Guide Section 13.3 on page 145), to create or change the attribute settings of devices used by the ML F.A.M.E..

❒ **Device** Menu

- ❍ *New* - This menu choice contains sub-menu choices allowing the ML F.A.M.E. operator to create new Instruments, Printers, Host computers and Samplers. Attention must be paid when defining new devices to the specific information required, e.g., when defining a new printer the physical name of the printer must be entered exactly as it is defined in the OS/2 system environment, i.e., if the name is listed in all upper case letters, then it must be defined in the ML F.A.M.E. software in the same case.
- ❍ *Change* - The Change menu choice allows the ML F.A.M.E. operator to modify the attributes of the device selected in the Device Presettings window.
- ❍ *Delete* - Removes the selected device from the ML F.A.M.E. database.

❒ **Connected Instrument** Menu (options may vary due to configuration).

- ❍ *View Configuration* - displays the currently connected instrument's configuration.
- ❍ *View Filters* - displays the currently connected instrument's installed photometric filters.
- ❍ *Entry Module* - dialog box allowing the temperature of the rear tower (front tower is always ambient) of this module to be set.

- *Incubator 1* - dialog box allowing the temperature of the front and rear towers of this module to be set.
- *Incubator 2* - as above.

❒ **Simulated Instrument** Menu - using the simulated instrument allows the user to run simulated scheduling of work lists. The options in this menu allow the user to define different configurations to achieve these simulated schedules and are virtually the same as the connected instrument options.

13.2.5 Software Presettings

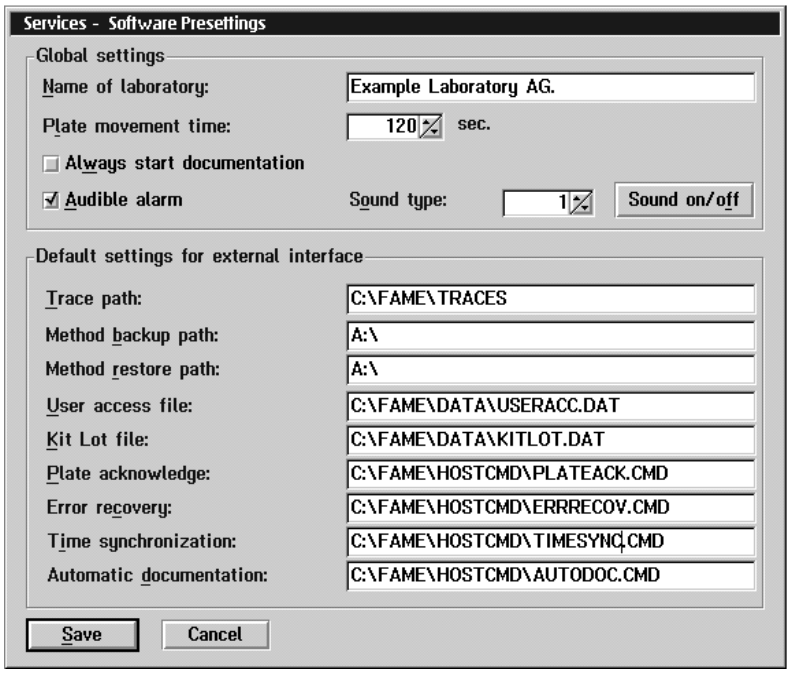


Figure 13.4 The Software Presettings Dialog Box

This dialog box allows ML F.A.M.E. operators, with sufficient access rights to change the settings of the ML F.A.M.E. software.

❒ **Global Settings**

- *Name of laboratory* - this name will be displayed on all information printed from the ML F.A.M.E. software.
- *Plate movement time* - defines the laboratory-specific time span which is required to transport the plate from the pipetting device to the ML F.A.M.E..
- *Always start documentation* - test documentation will be released automatically.
- *Audible alarm* - toggles audio prompts on or off (checked = on) when off the other sound options are non-selectable (grayed).
- *Sound type (Sounds on/off)* - this spin button allows the selection of individual sounds and the push button will disable the selected sound.

❒ External Interface Settings

- ❍ *Trace path* - specifies the path to where the trace files are stored and if applicable the file name.
- ❍ *Method backup path* - specifies the path to where backed-up methods are stored.
- ❍ *Method restore path* - specifies the path to where backed-up methods are restored to the ML F.A.M.E. database from.
- ❍ *User access file* - specifies the path to where, and the name of, the ML F.A.M.E. operator data file.
- ❍ *Kit Lot file* - specifies the path to where and the name of the kit lot data file.
- ❍ *Plate acknowledge* - specifies the name of the command file which informs the higher level system that the ML F.A.M.E. software has identified a plate and processing has begun.
- ❍ *Error recovery* - specifies the name of the command file which handles error recovery, i.e., if required common files cannot be opened the ML F.A.M.E. software will start this command file as a separate procedure.
- ❍ *Time synchronization* - specifies the name of the command file which will ensure the time of the ML F.A.M.E. workstation matches that of the higher system.
- ❍ *Automatic documentation* - When the command file is defined, an ASTM file is generated in addition to the documentation jobs defined in a test's method, with the following documentation format options:

  - Well trace
  - Test trace
  - Lowest trace priority (includes all trace messages)

  This documentation job will be processed independently of the documentation jobs defined for the method.

  The command file is a script that will transfer the ASTM file to a specified location, e.g. a network drive or host system. An important part of this command file is its confirmation to the ML F.A.M.E. of success or failure of delivery of this ASTM file.

  This is done using an executable file called "FAM_RTC.EXE" which is used to confirm the transfer. This file must be called in the command file (defined in the Automatic documentation entry field in the software presettings dialog box).

  Parameters of FAM_RTC.EXE:

  Parameter 1: result file name to be confirmed (without path)

  Parameter 2: 0 for positive confirmation
  1 for negative confirmation

ATTENTION
When the time synchronization has been defined, it is not allowed to run work lists when the switch to and from daylight saving time is made. Drive A: or B: must not be defined as the path for time synchronization.

ATTENTION
The following explanation of the results file transfer is for advanced users only and command or system related files should never be edited.

The example given in the following pages is only a guide line.

Due to various network/system configuration options it is the responsibility of the ML F.A.M.E. operator and system administrator to validate any such data transfer process.

Example: **`FAM_RTC 22133517 0`** /* for positive confirmation */

If the transmission is not confirmed within the result file transmission time-out time, the user software considers the transmission as not successful. The test status is not set to documented.

Example of a File Link Command

The file link command `myhost.cmd` will be called by the user software as defined in the Device Presettings dialog box or in the AUTODOC.CMD file with two additional parameters.

OS/2 file link command script:

```
REM  ********************************************************************
REM   Filename      : MyHost.cmd                                          *
REM   ********************************************************************
REM   Description:
REM   Send the file (path and name passed in with parameter 1 and 2) to
REM   a remote network resource utilizing a simple copy command.
REM   ********************************************************************
REM   Assume that a user is already logged on to the network.
REM   If not, logon to the network here.
REM   ********************************************************************

REM   ********************************************************************
REM   Open the network resource to use if not automatically assigned during
REM   logon
REM   ********************************************************************
      net use t: \hostres
      if errorlevel 1 goto nosuccess

REM   ********************************************************************
REM   copy the file to the network drive t:
REM   ********************************************************************
      copy %1%2 t: /v
      if errorlevel 1 goto nosuccess

REM   ********************************************************************
REM   confirm successful transmission to FAME software
REM   ********************************************************************
      fam_rtc %2 0

REM   ********************************************************************
REM   Start an application on your Host to tell your Host application,
REM   that a result file was sent.
REM   ********************************************************************
      net run t:\pick_res %2
      goto delres

REM   ********************************************************************
REM   if the copy failed, one could retry until copy is successful. If all
REM  retries failed, confirm to the Summit Processor software that the transmission
```

```
REM   failed.
REM   ***************************************************************
      :nosuccess
          fam_rtc %2 1

REM   ***************************************************************
REM   Delete the t-drive resource, logoff from the network if login
REM   was performed within this file link command.
REM   ***************************************************************
      :delres
          net use t: /d
      :end

REM   ***************************************************************
REM   End of example
REM   ***************************************************************
```

13.2.6 Set System Time

The ML F.A.M.E. software allows two ways of setting the system time.

- ❒ By using the Time Synchronization macro command file to get the time from a higher level system.
- ❒ By setting the system time using the **Set System Time** menu choice from the **Services** menu in the **Main** ML F.A.M.E. window.

NOTE
To use this function the time synchronization entry in the Software Presettings dialog box (See section 13.2.5 on page 13-142) must be deleted and the dialog box saved.
Also, it is only possible to use this function if the instrument status is either No instrument or Idle.

13.3 Access Rights

Due to the complex nature and flexibility of the ML F.A.M.E. software it is necessary to allocate various access rights to the different ML F.A.M.E. operators, therefore closing off some more complex sections which require extensive training to master and are easily affected by an inexperienced ML F.A.M.E. operator.

13.3.1 User Access Editor

When the installation option **User access editor off** is selected, access rights will be re-defined and can not be affected. When the installation option **User access editor on** is selected, it is possible to define laboratory specific user names, passwords and access rights. Access rights are assigned to individual ML F.A.M.E. operators when they are created. Six access levels exist (designated 1-6). Level 1 is the lowest level. ML F.A.M.E. operators with level-1 access rights can carry out only very limited tasks with the ML F.A.M.E.. Level 6 is the highest level. ML F.A.M.E. operators with level-6 access rights have access to all ML F.A.M.E. software functions. The system manager usually has level-6 access rights. The system manager can assign different access rights to different ML F.A.M.E. operators, thus allowing say one ML F.A.M.E. operator to run tests but not edit test data and another to run tests and also edit test data. ML F.A.M.E. operators must log in with the defined user name and password before actions can be undertaken with the ML F.A.M.E. software. The login designates the ***OPS*** operator's corresponding access rights.

NOTE

It is the responsibility of the system manager to create users and assign appropriate individual access rights. The table below summarizes the access rights required to carry out different functions with the system.

Description	Write	Read
Device presettings - Simulated Instrument	2	1
Delete method	6	1
Insert of trace messages by user	3	1
Test results	3	1
Verification	3	1
Routine work	3	1
Assignment editor	3	1
Stack definition	3	1
Maintenance	3	1
Change lock states	3	1
Documentation job definition of a method	3	1
Changing the barcode mask	4	1
Change System time	4	1
Edit the documentation formats	4	1
Restore of methods	4	1
Trace	4	1
Deletion of tests	4	3
Device presettings	4	1
Instrument status	4	1
Software presettings	4	1
Kit Lot Editor	5	2
View or edit method definitions	6	1
Backup of methods	6	1
View or edit global data for methods	6	1
User Access Editor	6	2
Firmware download	7	1

Chapter 14 ML F.A.M.E. Verification

Table of Contents

14.1 - Overview....148
14.1.1 - What is Verified....148
14.1.2 - Verification Statuses....149
14.1.3 - When are they Verified....149
14.1.4 - What is in a Verification Kit....150
14.1.5 - Precautions....150
14.1.6 - Archiving Verification Results....150
14.1.7 - Order of Verification....151
14.2 - Principles of Verification....152
14.2.1 - Photometer....152
14.2.2 - Dispenser....154
14.2.3 - Washer....155
14.2.4 - Incubator....157
14.2.5 - Statistical Definitions Used for Verification....158
14.2.6 - Absorbance Calculation (E)....158
14.2.7 - Volume Calculation (V)....159
14.2.8 - General Calculation Principles....159
14.2.9 - Acceptance Criteria....160
14.3 - Disposal of Consumable Items....163
14.3.1 - Verification Kit Maintenance....163
14.3.2 - Referencing the Photometer Check Plate....163
14.3.3 - Incubator Check Plate Calibration....163
14.3.4 - Decontamination....164
14.4 - The Verification Window....165
14.4.1 - Menu Choices....166

14.1 Overview

NOTE
A warning dialog box will be displayed giving 14 days notice of any required verification procedures.

Verification is an in-built self checking system of the functionality of the ML F.A.M.E.. All physical modules of the instrument are tested against predefined values using a verification kit with tested, known values.

These checks must be performed at a regular interval to ensure reliable operation of the ML F.A.M.E..

When the ML F.A.M.E. software has been installed with the **Verification restrictive** installation option, if any verification procedures have the status Required the ML F.A.M.E. will not perform any tests. Also, if any ML F.A.M.E. modules fail verification the module's status will remain Required and the instrument will be locked. However, individual incubator slots that have failed verification may be locked leaving all others active.

14.1.1 What is Verified

ATTENTION
Each verification procedure has an associated set of acceptance criteria. The user is responsible for taking corrective action whenever a verification result is out of range.

The following instrument functions are verified:

❒ **Photometer**

- ❍ plate positioning
- ❍ accuracy and short-term reproducibility for measuring channels A to H and reference channel
- ❍ stray light
- ❍ short-term drift
- ❍ infrared blocking

❒ **Dispensers**

- ❍ accuracy
- ❍ precision

❒ **Washer(s)**

- ❍ average residual volume
- ❍ maximum residual volume
- ❍ aspirating precision and accuracy

❒ **Incubators**

- ❍ temperature variations

14.1.2 Verification Statuses

- ❒ **Required** - ML F.A.M.E. non-functional. Some verification procedures must be run.
- ❒ **Completed** - ML F.A.M.E. Functional. Modules verified and criteria matched.
- ❒ **Open** - Module not present in current configuration and after first installation all modules will have the status open.

14.1.3 When are they Verified

❒ **Photometer**

- ❍ Upon initial instrument installation.
- ❍ Quarterly (every 90 days).
- ❍ After repair or service of the module.
- ❍ If liquid spillage occurred in the end module.
- ❍ When a filter is exchanged.
- ❍ When the end module is exchanged.

❒ **Dispenser**

- ❍ Upon initial instrument installation.
- ❍ Quarterly (every 90 days) per dispenser.
- ❍ After repair or service of the module.
- ❍ When the module is exchanged.

❒ **Washer**

- ❍ Upon initial instrument installation.
- ❍ Quarterly (every 90 days) per washer.
- ❍ After repair or service of the module.
- ❍ When a manifold is exchanged.
- ❍ When the module is exchanged.

❒ **Incubator**

- ❍ All slots upon initial instrument installation.
- ❍ All slots twice a year (every 180 days).
- ❍ After repair or service of the incubator module.
- ❍ After a slot is locked due to a temperature error.
- ❍ When the incubator module is exchanged.

After ML F.A.M.E. initialization a number of checks are made, one of these is to determine the verification interval statuses. The ML F.A.M.E. operator will be prompted if any verification procedures are required.

14.1.4 What is in a Verification Kit

The complete Verification Kit consists of the following items:

- ❒ Incubator/Photometer Verification Kit, containing:
  - ❍ Incubator Check Plate.
  - ❍ Photometer Check Plate.
    Diskette containing Photometer reference data.

NOTE
The Washer/Dispenser Verification Kit can be ordered as a separate item. Additional Incubator Check Plates may also be ordered.

- ❒ Washer/Dispenser Verification Kit, containing all consumable items required for the dispenser and washer verification procedures:
  - ❍ Four Dye Solutions (Check Solutions A, B, C and D) sufficient to verify 3 Washers and 3 Dispensers or combinations of.
  - ❍ Washer and Dispenser Check Plates.
  - ❍ Reagent Container Set.
  - ❍ Disposable Syringe Set.

The following item is also required but is not included in the Verification Kit:

- ❒ Calibrated hand pipette(s) (50, 100 and 200 μl volume).

14.1.5 Precautions

As is the case with all operation of the ML F.A.M.E., it is recommended to follow Good Laboratory Practice (GLP) standard. In addition to this standard:

- ❍ Avoid touching the undersides of the photometer, dispenser and washer check plates and ensure that they are completely clean, dry and free from particles.
- ❍ The photometer and incubator check plates are fragile so please handle them with care. Take the necessary precautions when handling the photometer check plate.
- ❍ The photometer and incubator check plates must be decontaminated before they are returned for referencing/calibration.
- ❍ The washer and dispenser check plates may only be used once and then discarded.

14.1.6 Archiving Verification Results

A record of all verification runs should be kept for future reference and to aid any possible error tracing. Use the print functions described in 14.4.1 on page 14-166 to document the verification run immediately upon completion.

14.1.7 Order of Verification

Always verify the photometer before the dispenser and then the washer. Verify the washer and dispenser on the same day using the same check solutions.

Since the washer and dispenser verification procedures use the same check solutions, a syringe dedicated to a specific check solution can be used for both verification procedures.

14.2 Principles of Verification

14.2.1 Photometer

ATTENTION
Photometer filters 620nm and 405nm must be present to perform verification.

Figure 14.1 explains the purpose of the filters on the photometer check plate. The gray-scale filters have absorbance values of approximately 0.3, 0.6, 1.0 and 2.0 OD (at wavelengths > 400 nm).

Due to variations in the glass, each photometer check plate has its own set of reference values which must be loaded into the ML F.A.M.E. database. In order to compensate for any drift in characteristics, the photometer check plate has to be referenced once a year at the manufacturer's site and the new reference values loaded into the database (see section 14.3.2 on page 14-163).

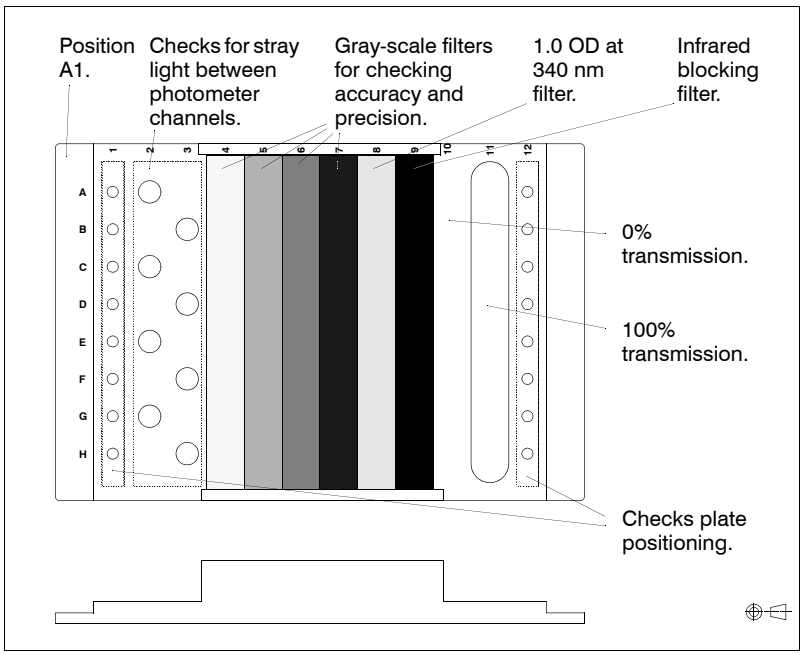

Position A1.
Checks for stray light between photometer channels.
Gray-scale filters for checking accuracy and precision.
1.0 OD at 340 nm filter.
Infrared blocking filter.
0% transmission.
100% transmission.
Checks plate positioning.

Figure 14.1 Photometer Check Plate

For each well position on the photometer check plate, five measurements are made using each photometer filter (340, 405, 450, 492, 620 nm and, if installed, 570, 610 and 690 nm). The mean values of the five measurements are used to determine the parameters in the following table:

Parameter	*Rows Used*	*Description*
Plate positioning	1 & 12	Checks the positioning of the plate in the optical axis at 405 nm. The diameter of the check holes are such that when the plate is correctly positioned, only 10 mOD may be absorbed.

Parameter	***Rows Used***	***Description***
Accuracy	4 - 8	Checks the measured values against the reference values of the check plate. Each gray-scale filter and filter wavelength has specific tolerance values.
Short-term reproducibility	6	Calculates the variation in 5 consecutive measurements. Measured as coefficient of variation (CV(%)). Tested at wavelengths ≥ 400 nm.
Infrared (IR) blocking	9	This row only lets through infrared light. In conjunction with the IR-filter in the photometer, no light should be detected. Tested at 620 nm.
Stray light	2 & 3	Checks for cross-talk between photometer channels at 620 nm. The checker-board configuration of the two rows tests whether light from one photometer channel is detected by an adjacent one.
Short-term drift	6	Calculates the variation between the measurements made during the current verification and the measurements from the previous verification. Note: only calculated if previous verification was performed within 10 days of the current verification. Tested at wavelengths ≥ 400 nm.

14.2.2 Dispenser

The dispenser check plate is a flat-bottom microplate. Six rows are hand pipetted; the remaining wells are pipetted by the dispenser. Figure 14.3 shows the layout. The ODs of the hand-pipetted wells are measured with the photometer and used as reference values.

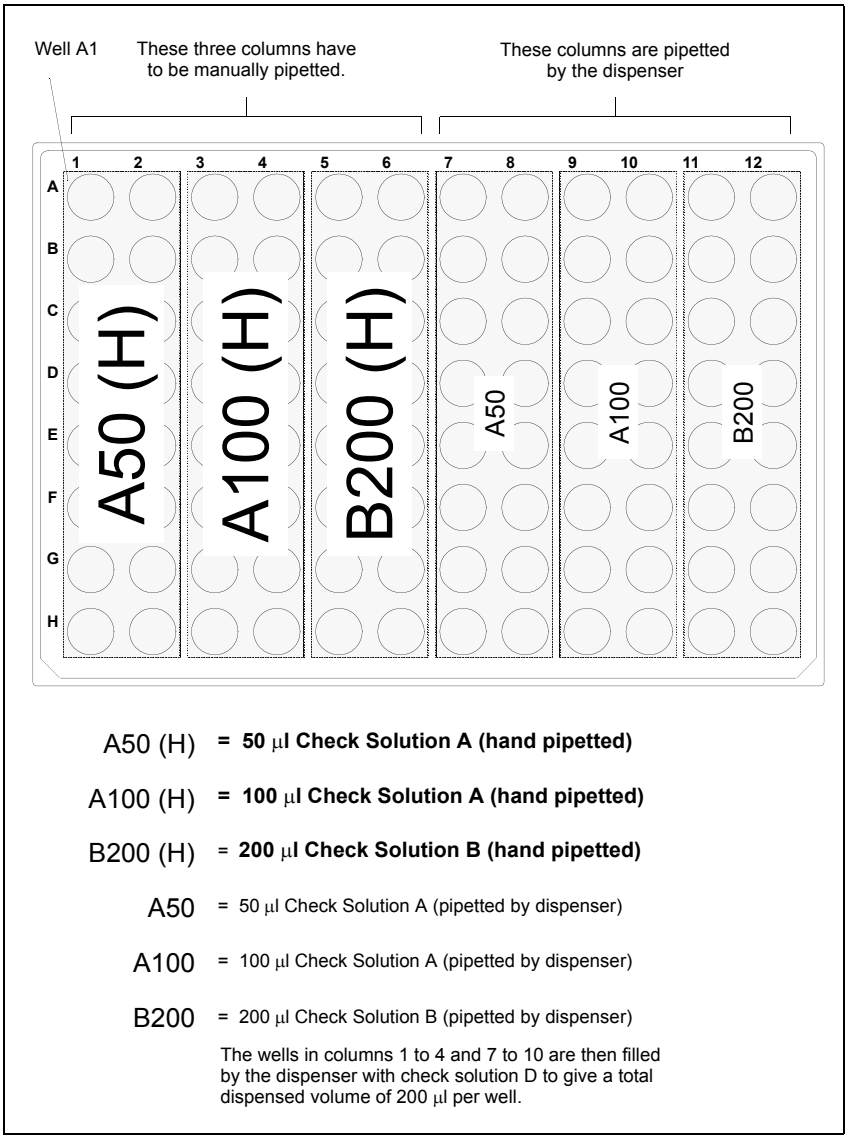

Well A1
These three columns have to be manually pipetted.
These columns are pipetted by the dispenser
1 2 3 4 5 6 7 8 9 10 11 12
A
B
C
D
E
F
G
H
A50 (H)
A100 (H)
B200 (H)
A50
A100
B200
A50 (H) = 50 µl Check Solution A (hand pipetted)
A100 (H) = 100 µl Check Solution A (hand pipetted)
B200 (H) = 200 µl Check Solution B (hand pipetted)
A50 = 50 µl Check Solution A (pipetted by dispenser)
A100 = 100 µl Check Solution A (pipetted by dispenser)
B200 = 200 µl Check Solution B (pipetted by dispenser)
The wells in columns 1 to 4 and 7 to 10 are then filled by the dispenser with check solution D to give a total dispensed volume of 200 µl per well.

Figure 14.2 Plate Layout for Dispenser Check

Since the absorbance is proportional to the volume of liquid in the well, the dispensing accuracy can be determined using a simple calculation.

The dispensing precision is also indirectly calculated from the variation in absorbance.

The following parameters are calculated:

Parameter		*Description*
Accuracy:	50 µl 100 µl 200 µl	Compares the volumes dispensed by the dispenser with the volumes of the hand pipetted wells. Measured as a percentage of the nominal dispensed volume.
Precision:	50 µl 100 µl 200 µl	Measures the variation in dispensed volume. Units: (CV(%)).

14.2.3 Washer

200 µl of check solution B is pipetted into 24 wells of the wash check plate (rows 1, 2, & 3).

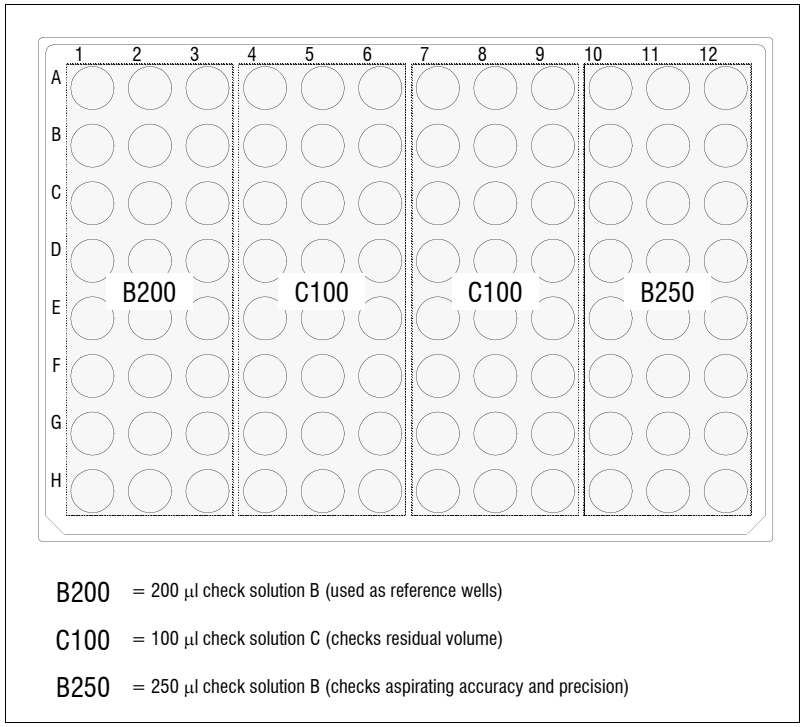


Figure 14.3 Plate Layout for Washer Check

The OD value of these wells are measured with the photometer and used as reference values. The verification procedure is then as follows:

Residual Volume

The wells to be tested (rows 4 to 9) are filled with 100 µl of a concentrated dye solution (check solution C).

The wells are then aspirated. 200 µl of colorless solution (check solution D) is then dispensed into the aspirated wells.

The absorbance of the wells is then measured with the photometer.

By comparison with the values of the reference wells and the known concentrations of the check solutions, the residual volume can be calculated.

Aspirating Accuracy and Precision

The wells to be tested (rows 10, 11 & 12) are pipetted with 250 µl of check solution B using the dispenser.

The manifold height is set such that the aspirating needles are at the 200 µl liquid level and the wells are then aspirated.

The absorbance of each well is then measured with the photometer and the mean calculated.

By comparing the mean of the reference wells with the mean of the wells being tested, the aspirating accuracy is measured.

The aspirating precision is calculated by measuring the variation in absorbance of the tested wells.

The table below summarizes the parameters measured.

Parameter	***Description***
Average residual volume	Using a dilution, the mean of the ODs of the tested wells is compared with that of the reference wells. Units: µl.
Maximum residual volume	Using a dilution, the maximum OD of the tested wells is compared with the mean of the reference wells. Units: µl.
Aspirating accuracy	Compares the mean liquid level of the wells being tested with those of the reference wells. Units: %.
Aspirating precision	Calculates the variation in liquid levels of the tested wells. Units: CV (%).

14.2.4 Incubator

The incubator check plate has been referenced at the manufacturer's site and is supplied with a temperature offset value which must be entered into the system via a dialog box (carried out yearly).

The formula for the temperature offset is as follows:

$$T_o = T_c - T_m$$

where T_o = temperature offset of incubator check plate
T_c = check plate temperature
T_m = maximum temperature measured by incubator check plate

The incubators should always be verified at their normal operating range in the laboratories daily work.

Temperature range for verification

Ambient to 45°C, this can be set in the device presettings window.

The incubator check plate is loaded into a selected incubator slot and incubated for 30 minutes.

During verification the following values are determined:

Check plate temperature

The actual temperature, which is calculated as follows:
maximum temperature measured and displayed by the incubator check plate + temperature offset of incubator check plate.

ATTENTION
The temperature of the incubator check plate must be lower than the target temperature of the slot.

Between each incubator verification the incubator check plate must be switched off and then on again to clear its memory.

Target temperature

Temperature which is defined in the user software for the corresponding incubator (device pre-settings).

Reported temperature

Temperature measured by the sensor in the incubator slot which is similar to the reported temperature 'incubation finished' in the test trace.

The acceptance criteria are calculated as follows (for further information See section 14.2.9 on page 14-160):

❒ Temperature-controlled incubation

❍ The temperature deviations of the target temperature or of the reported temperature are compared with the check plate temperature.

❒ Ambient incubation

❍ The check plate temperature and the reported temperature are compared with the ambient temperature range.

14.2.5 Statistical Definitions Used for Verification

Mean ($\bar{x}$)

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n}$$

where n = number of values
x_i = the i^{th} value

Standard Deviation (*s*)

$$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$$

where n = number of values
x_i = the i^{th} value

Precision (Coefficient of variation (*CV (%)*))

$$CV = \frac{s}{\bar{x}} \cdot 100$$

Accuracy (*R*)

For the washer and dispenser, the following formula applies:

$$R = \frac{\bar{x} - x_t}{x_t} \cdot 100$$

measured as a percentage (%),

where x_t = target value

For the photometer, the following formula applies:

$$R = x_m - x_r$$

measured in O.D.,
where x_m = measured value
x_r = reference value

14.2.6 Absorbance Calculation (*E*)

$$E = \varepsilon \cdot c \cdot d$$

where ε = coefficient of absorbance
c = concentration
d = distance (thickness of medium)

14.2.7 Volume Calculation (*V*)

Assuming a cylindrical well,

$$V = \pi \cdot r^2 \cdot h$$

where r = well radius
h = liquid height (in this case, *d* in the absorbance formula).

14.2.8 General Calculation Principles

Calculating the Volume of Liquid in a Well

Given the absorbance of a known volume of solution (hand pipetted wells for dispenser verification, wells dispensed by dispenser for washer verification) and assuming that the same concentration of the same solution is used, the absorbance of an unknown well can be measured to determine the volume of liquid contained in it. Assuming that all wells in a plate have the same diameter, the absorbance will be proportional to volume of solution. The following formula therefore applies:

$$V_2 = \frac{E_2 \cdot V_1}{E_1}$$

where V_2 = the unknown volume
E_2 = absorbance of the unknown volume
V_1 = the known volume
E_1 = absorbance of the known volume

14.2.9 Acceptance Criteria

14.2.9.1 Photometer

ATTENTION
The combined tolerances listed as "sources of variation" area are accounted for in the user verification acceptance criteria.

The table below lists examples of nominal OD values for the photometer check plate using the standard photometer filters. The exact reference values are supplied on diskette with the photometer check plate (units: OD).

Filter	*Row 4*	*Row 5*	*Row 6*	*Row 7*	*Row 8*
340 nm	-	-	-	-	1.0
405 nm	0.265	0.580	1.2	2.2	-
450 nm	0.265	0.540	1.1	2.0	-
492 nm	0.270	0.550	1.0	2.0	-
570 nm	0.280	0.560	1.1	2.0	-
610 nm	0.290	0.565	1.1	2.0	-
620 nm	0.280	0.540	1.0	1.9	-
690 nm	0.265	0.460	0.95	1.5	-

Accuracy

The acceptance criteria are assigned per wavelength and are listed in the table below (units: m OD).

Filter	*Row 4*	*Row 5*	*Row 6*	*Row 7*	*Row 8*
340 nm	-	-	-	-	$\leq \pm 50$
405 nm	$\leq \pm 9$	$\leq \pm 15$	$\leq \pm 50$	$\leq \pm 120$	-
450 nm	$\leq \pm 16$	$\leq \pm 25$	$\leq \pm 60$	$\leq \pm 120$	-
492 nm	$\leq \pm 9$	$\leq \pm 15$	$\leq \pm 25$	$\leq \pm 100$	-
570 nm	$\leq \pm 10$	$\leq \pm 15$	$\leq \pm 25$	$\leq \pm 100$	-
610 nm	$\leq \pm 10$	$\leq \pm 15$	$\leq \pm 25$	$\leq \pm 100$	-
620 nm	$\leq \pm 7$	$\leq \pm 15$	$\leq \pm 25$	$\leq \pm 100$	-
690 nm	$\leq \pm 16$	$\leq \pm 25$	$\leq \pm 60$	$\leq \pm 120$	-

Plate Positioning

Row 1 & 12: $\leq$ 10 mOD (measured at 405 nm)

Short-Term Reproducibility

Row 6: $\leq$ 0.3% CV (measured at all filter wavelengths $\geq$ 400 nm).

Stray Light

Checker-board configuration row 2 and 3:

Š 3 OD for blocking positions
< 10 mOD for holes (measured at 620 nm)

Infrared Blocking

Row 9: ≥ 3 OD (measured at 620 nm)

Short-Term Drift

Row 6: < ± 10 mOD (measured at all filter wavelengths ≥ 400 nm).

14.2.9.2 Dispenser

Accuracy

$\Delta V_2(\%) = \Delta E_2(\%) + \Delta E_1(\%) + \Delta V_1(\%)$

Volume	*Sources of Variation*	*Acceptance Criteria*
50 µl	Photometer accuracy, dilution, meniscus, edge effects with small volumes, hand pipette accuracy.	≤ ± 5%
100 µl	as above	≤ ± 5%
200 µl	as above	≤ ± 5%

Precision

$\Delta V_2(\%) = \Delta E_2(\%) + \Delta V_1(\%)$

Volume	*Sources of Variation*	*Acceptance Criteria*
50 µl	Photometer precision, edge effects with small volumes, meniscus.	≤ 5%
100 µl	as above	≤ 5%
200 µl	as above	≤ 5%

14.2.9.3 Washer

Parameter	*Sources of Variation*	*Acceptance Criteria*
Average residual volume	Dilution, meniscus, inhomogenity, edge effects with small volumes (< 25 µl), dispenser accuracy at 200 µl.	≤ 10 µl
Maximum residual volume	as above.	no well > 20 µl
Aspirating accuracy	Meniscus, edge effects with small volumes (< 200 µl), dispenser accuracy at 200 µl, manifold aspirating height, plate height (slant).	≤ ± 20%
Aspirating precision	Meniscus, edge effects with small volumes (< 200 µl), manifold aspirating height, plate height (slant).	≤ 15%

14.2.9.4 Incubator

Precision of incubator check plate: 0.3 °C

Temperature-controlled incubator (35 to 45 °C).

Parameter	*Sources of Variation*	*Acceptance Criteria*
Temperature deviation of target temperature - check plate temperature	Precision of incubator check plate.	≤ ± 1.0 °C
Temperature deviation of reported temperature - check plate temperature	ditto	≤ ± 1.0 °C

Ambient incubator (15 to 30 °C).

Parameter	*Sources of Variation*	*Acceptance Criteria*
Check plate temperature	Precision of incubator check plate.	15 to 30 °C
Reported temperature	ditto	15 to 30 °C

14.3 Disposal of Consumable Items

Consumable items used for verification (e.g. check plates, syringes, reagent containers, waste fluid) must be disposed of in accordance with the rules of Good Laboratory Practice.

14.3.1 Verification Kit Maintenance

In order to produce valid verification results, the following maintenance procedures have to be carried out at the specified intervals:

- ❒ Referencing of the photometer check plate (see section 14.3.2).
- ❒ Incubator check plate calibration (see section 14.3.3).
- ❒ Re-calibration of the hand pipette(s) (as recommended by manufacturer).

14.3.2 Referencing the Photometer Check Plate

Required interval:

Once a year (before the date given on the declaration of quality expires).

The photometer check plate must be returned to the dealer at the specified interval for referencing. This is necessary because the characteristics of the filters can drift with time.

The newly-referenced plate will then be returned with a diskette containing the new reference values.

The new reference values must then be loaded into the computer.

14.3.3 Incubator Check Plate Calibration

Required interval:

Once a year (before the date given on the declaration of quality expires).

The incubator check plate must be returned to the dealer at the specified interval for calibration.

The newly-calibrated plate will then be returned with a declaration of quality containing the temperature offset value.

The new temperature offset value must then be entered into the computer.

14.3.4 Decontamination

The photometer and incubator check plates must be decontaminated at regular intervals and also before they are returned for referencing/calibration. The procedure for both items is the same.

Recommended interval:

After each use.

Procedure:

Wipe the surfaces gently with a lint-free cloth soaked in ethanol (70%).

14.4 The Verification Window

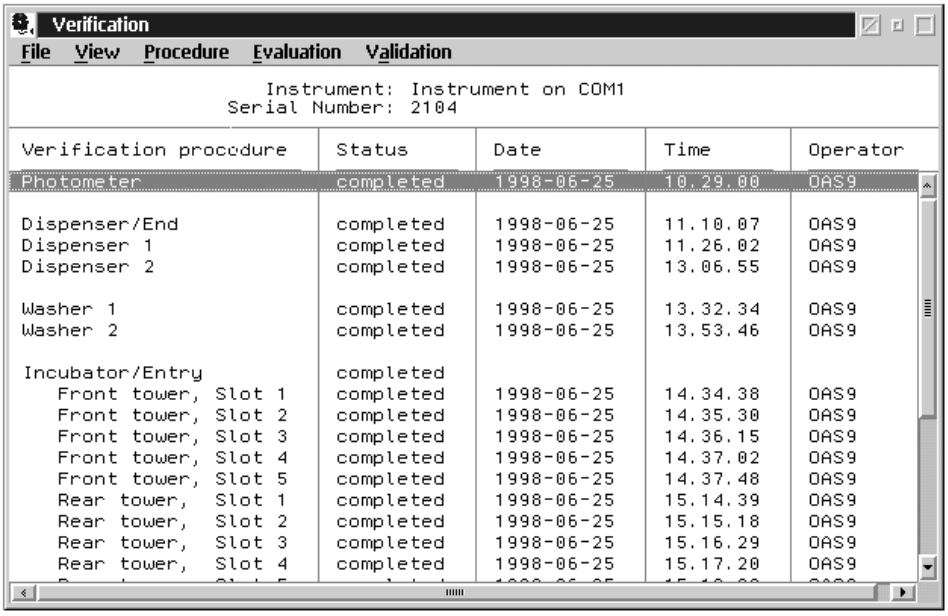

Verification
File View Procedure Evaluation Validation
Instrument: Instrument on COM1
Serial Number: 2104
Verification procedure | Status | Date | Time | Operator
Photometer completed 1998-06-25 10.29.00 OAS9
Dispenser/End completed 1998-06-25 11.10.07 OAS9
Dispenser 1 completed 1998-06-25 11.26.02 OAS9
Dispenser 2 completed 1998-06-25 13.06.55 OAS9
Washer 1 completed 1998-06-25 13.32.34 OAS9
Washer 2 completed 1998-06-25 13.53.46 OAS9
Incubator/Entry completed
Front tower, Slot 1 completed 1998-06-25 14.34.38 OAS9
Front tower, Slot 2 completed 1998-06-25 14.35.30 OAS9
Front tower, Slot 3 completed 1998-06-25 14.36.15 OAS9
Front tower, Slot 4 completed 1998-06-25 14.37.02 OAS9
Front tower, Slot 5 completed 1998-06-25 14.37.48 OAS9
Rear tower, Slot 1 completed 1998-06-25 15.14.39 OAS9
Rear tower, Slot 2 completed 1998-06-25 15.15.18 OAS9
Rear tower, Slot 3 completed 1998-06-25 15.16.29 OAS9
Rear tower, Slot 4 completed 1998-06-25 15.17.20 OAS9

Figure 14.4 Verification Window (View 1)

View 1 shows the current verification status of each instrument module and is the default view.

View 2 shows the current verification kit elements and data status and their expiry dates.

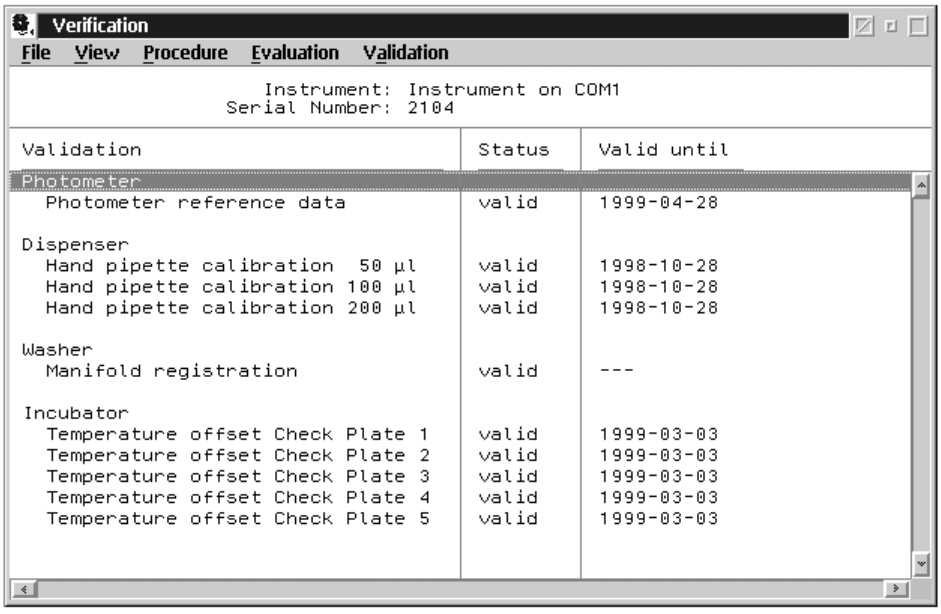

Verification
File View Procedure Evaluation Validation
Instrument: Instrument on COM1
Serial Number: 2104
Validation | Status | Valid until
Photometer
Photometer reference data valid 1999-04-28
Dispenser
Hand pipette calibration 50 µl valid 1998-10-28
Hand pipette calibration 100 µl valid 1998-10-28
Hand pipette calibration 200 µl valid 1998-10-28
Washer
Manifold registration valid ---
Incubator
Temperature offset Check Plate 1 valid 1999-03-03
Temperature offset Check Plate 2 valid 1999-03-03
Temperature offset Check Plate 3 valid 1999-03-03
Temperature offset Check Plate 4 valid 1999-03-03
Temperature offset Check Plate 5 valid 1999-03-03

Figure 14.5 Verification Window (View 2)

14.4.1 Menu Choices

❒ **File Menu**

- ❍ *Print View*
  Prints the information displayed in the current view (on the OS/2 default printer).
- ❍ *Print Details*
  Prints detailed information on the selected module.
- ❍ *Print All Details*
  Prints detailed information on all modules.
- ❍ *Abort Verification Run*
  Aborts the current Verification runs.
- ❍ *Close (Alt+F4).*
  It is not possible to close the **Verification** window while a verification run is active. Select the **Abort Verification Run** choice before selecting this option.

❒ **View Menu**

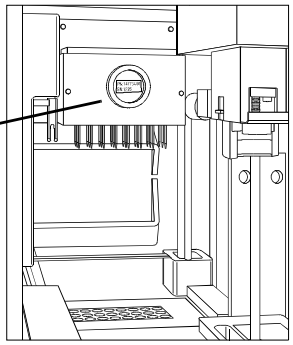
- ❍ *Actual Verification Statuses*
  Displays a list of all verifiable modules, their sub-modules and their current status.
- ❍ *Previous Verification Statuses*
  Displays a list of all verifiable modules, their sub-modules and their status prior to the most recent verification run.
- ❍ *Before Previous Verification Statuses*
  Displays a list of all verifiable modules, their sub-modules and their status prior to the previous verification run.
- ❍ *Validation Statuses*
  Displays the validity status and expiry date of the elements and logged data of the verification kit.

❒ **Procedure Menu**
All sub-menu choices will initiate the verification procedure for the applicable ML F.A.M.E. module.

❒ **Evaluation Menu**
All sub-menu choices will displays a dialog box giving information on the complete verification run of the applicable module.

❒ **Validation Menu**
Before any verification procedures can be started the information required here must be entered. It is *not possible* to verify a module without registering this data.

- ❍ *Load Photometer Reference Data*
  When selected the ML F.A.M.E. operator will be prompted to insert the Photometer Reference Data Diskette. Predefined data will be loaded into the ML F.A.M.E. database and used as the criteria for verification.



- *Dispenser*
  Displays a dialog box where the ML F.A.M.E. operator must enter information about the hand pipetting device used to establish the check volumes by which the dispenser is verified.
- *Washer*
  Displays a dialog box where the user must enter the serial number of the washer manifold in the instrument being verified.
- *Incubator*
  Displays a dialog box where the ML F.A.M.E. operator must enter information about the Incubator check plate being used for the verification.

Chapter 15 ML F.A.M.E. Maintenance

Table of Contents

15.1 - Overview....170
15.1.1 - When to run Maintenance Procedures....170
15.1.2 - What is Required for Maintenance....170
15.1.3 - The Maintenance Window....171
15.1.4 - Menu Choices....171
15.1.5 - Maintenance Statuses....172
15.1.6 - Maintenance Procedures....173
15.1.7 - Maintenance Requirements....175
15.1.8 - Washer Decontamination....180
15.1.9 - Incubator Decontamination....181

15.1 Overview

The ML F.A.M.E. requires a number of periodic maintenance routines to be run in order to ensure safe and reliable operation.

These maintenance routines are mandatory and without their completion no tests are processable on the ML F.A.M.E..

15.1.1 When to run Maintenance Procedures

- ❒ Cold Start - must be run after the first ML F.A.M.E. initialization of the day or after every 24 hours of operation.
- ❒ Daily - before ML F.A.M.E. shut-down if it has not been run for one day.
- ❒ Weekly - before ML F.A.M.E. shut-down if it has not been run for one week.
- ❒ Monthly - before ML F.A.M.E. shut-down if it has not been run for one month.

When any maintenance routine is required it is not possible to perform tests.

NOTE
If the ML F.A.M.E. operator declines to run either, weekly or monthly maintenance before shut down, upon the next initialization these routines must be run.
If three weekly maintenance procedures have been run in a month, the forth can be skipped (only if the monthly procedure is run) as all required procedures are covered in the monthly maintenance procedure.

15.1.2 What is Required for Maintenance

- ❒ Disposable latex gloves
- ❒ Protective glasses
- ❒ Lab coat
- ❒ Paper towels
- ❒ Ethanol (70%)
- ❒ Rinse solution = Deionized water
- ❒ NaCl solution = Deionized water containing 0.5 g/l NaCl
- ❒ Ultrasonic bath (optional)
- ❒ Disinfectant = Microlab™ Detergent and Disinfectant or Microcide SQ (only available in the USA)
- ❒ Microlab™ Disinfectant Spray

NOTE
Use cleaning, disinfecting and decontaminating fluids in accordance with manufacturers' instructions.
Do not use disinfecting materials which contain hypochlorite (Javelle water, Chlorox) or bleaching fluids.

NOTE
Prepare disinfectant fluids according to their labelling.

15.1.3 The Maintenance Window

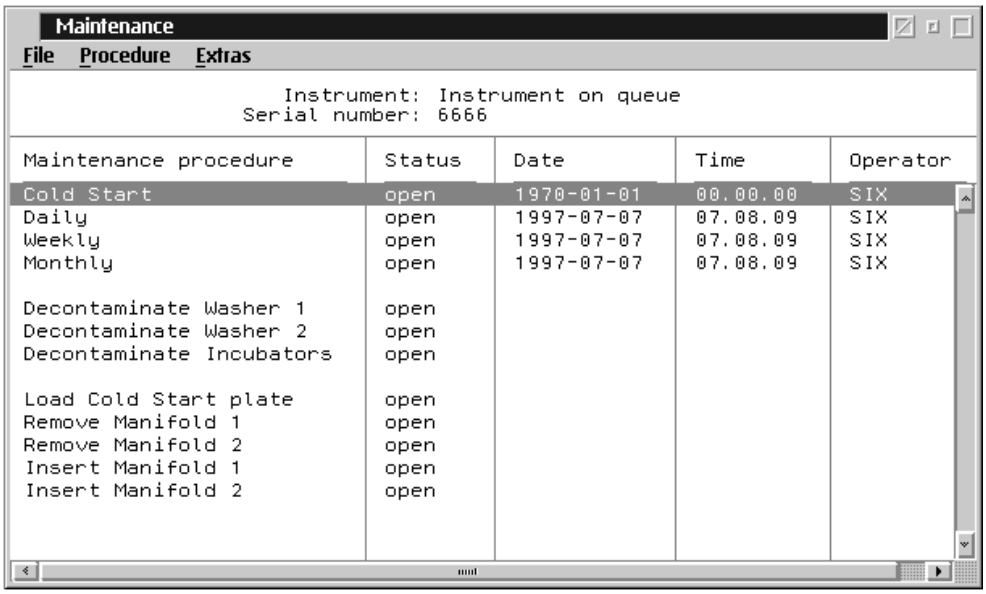


Figure 15.1 Maintenance Window

In this window the ML F.A.M.E. operator can view the Maintenance status of each ML F.A.M.E. module and access the necessary commands to perform all maintenance-related routines.

15.1.4 Menu Choices

❒ **File Menu**

- ❍ *Print*
  Prints the information displayed in the current view (on the OS/2 default printer).
- ❍ *Abort Maintenance Procedure*
  Halts all maintenance actions regardless of how they were started.
- ❍ *Close*
  It is not possible to close the Maintenance window while a maintenance run is active. Select the Abort Maintenance Run choice before selecting this option.

❒ **Procedure Menu**
All sub-menu choices will initiate the applicable maintenance procedure (all maintenance procedures are fully guided by on-screen ML F.A.M.E. operator instructions, for further information See section 15.1.7.1 on page 15-175).

❒ **Extras Menu**

❍ *Remove Manifold* ⏻
Washer 1
Washer 2
Washer 1 & 2

This procedure prepares the selected washer manifold for removal from the ML F.A.M.E. for maintenance, replacement, etc., by lowering the manifold to an accessible position.

❍ *Insert Manifold* ⏻
Washer 1
Washer 2
Washer 1 & 2

This procedure prepares the ML F.A.M.E. to accept the selected washer manifold for reinsertion after maintenance, replacement, etc., then raises the manifold to its operational position.

❍ *Decontaminate* ⏻
Washer 1
Washer 2
Washer 1 & 2

When one of these choices is selected the ML F.A.M.E. operator will be guided through a decontamination procedure by various on-screen action prompts.

Incubators

When this choice is selected all incubator slots are raised (or lowered) to an accessible position and their doors opened to allow access for decontamination.

❍ *Load Cold Start Plate*
Installs the cold start plate to its operational position in Incubator 2's storage position (situated on top of the incubator).

15.1.5 Maintenance Statuses

Three maintenance statuses exist:

Required:
maintenance procedure is overdue or carried out unsuccessfully.

Completed:
maintenance procedure carried out successfully.

Open:
after first installation of ML F.A.M.E. software, if the serial number of the instrument has changed, if a work list is active and if the ML F.A.M.E. operator has insufficient access rights.

15.1.6 Maintenance Procedures

For instructions on accessing the maintenance routines see Cook Book Section - 8.1.1 on page 70.

15.1.6.1 Every Day (Approx. Duration: 13-25 minutes)

❒ **Cold Start Maintenance.**

- ❍ Approx. duration: 5 minutes.
- ❍ Must be carried out in the morning prior to any ML F.A.M.E. test processing.
- ❍ Checks the functions of, and rinses the Washer(s).

❒ **Renew Defective Syringes** (see Cook Book Section - Table 8.1.3.1 - on page 74).

- ❍ Approx. duration: 1-3 minutes.
- ❍ Check syringes for tightness, i.e. formation of air bubbles, water in reagent container.
- ❍ Replace if applicable

❒ **Daily Maintenance Routine.**

- ❍ Approx. duration: 5-10 minutes.
- ❍ Must be carried out at the end of each working day prior to system shut down.
- ❍ Rinses the washer system, fills the wash shell and immerses the needles of the manifold in fluid to prevent crystallization.

❒ **Clean Waste Container** (see Cook Book section “Waste containers and waste caps” on page 8-76).

- ❍ Approx. duration: 2 minutes.
- ❍ Decontaminate the waste with a suitable decontamination fluid, empty the container, rinse with tap water and leave to dry.

❒ **Clean Syringes** (see Cook Book section “Clean/dispose of syringes” on page 8-74).

- ❍ Approx. duration: 5-10 minutes.
- ❍ Fill syringe with deionized water.
- ❍ Stand the syringe upright in the reagent container overnight.

15.1.6.2 Every Week (Approx. Duration: 40-50 minutes)

For instructions on accessing the maintenance routines see Cook Book Section - 8.1.1 on page 70.

❒ **Clean Wash System** (see Cook Book section Table 8.1.3.2 - "Manual Cleaning Weekly Maintenance" on page 8-75).

- ❍ Approx. duration: 20 minutes.
- ❍ Must be carried out on the last working day of the week prior to ML F.A.M.E. system shut down.
- ❍ Rinses all wash channels and tubings with a solution of *Disinfectant* and then rinses them with NaCl solution and deionized water.
- ❍ This procedure will solute any wash system obstructions.

❒ **Clean the** ML F.A.M.E. (see Cook Book section "Clean instrument housing, entry lift, entry stack and plate transport system" on page 8-75).

- ❍ Approx. duration: 5 minutes.
- ❍ Clean all ML F.A.M.E. surfaces with *Microlab™ Disinfectant Spray.*
- ❍ Photometer lens block should always be cleaned with a lint-free cloth soaked in 70% ethanol.

NOTE
Each time the wash containers are cleaned check for any growth or bacterial build up. If found replace wash containers with new ones.

❒ **Clean Wash Fluid Containers** (see Cook Book section "Wash fluid containers" on page 8-76).

- ❍ Approx. duration: 5-10 minutes.
- ❍ Rinse containers with deionized water.
- ❍ Leave containers to dry over weekend.

❒ **Clean Reagent Containers** (see Cook Book section "Reagent containers" on page 8-76).

- ❍ Approx. duration: 5-10 minutes.
- ❍ Clean with tap water not hotter than 50°C or with laboratory washing equipment.
- ❍ Rinse with deionized water, empty and leave to dry.

❒ **Replace All Syringes** (see Cook Book section "Renew syringes" on page 8-76).

- ❍ Approx. duration: 5 minutes.

15.1.6.3 Every Month (Approx. Duration: 1 hour 20 minutes - 1 hour 25 minutes)

For instructions on accessing the maintenance routines see Cook Book Section - 8.1.1 on page 70.

- ❒ **Washer Decontamination** (See section 15.1.8 “Washer Decontamination” on page 15-180).
  - ❍ Approx. duration: 35-40 minutes.
  - ❍ Must be carried out at the end of the working day at the end of every month prior to ML F.A.M.E. system shut down.
  - ❍ Rinses and soaks all wash channels, tubings and the waste extraction system using a solution of a suitable disinfectant and then rinses them with NaCl solution and deionized water.
- ❒ **Clean Washer Manifold** (see Cook Book section 8.1.2 “Washer Manifold” on page 8-71).
  - ❍ Approx. duration: 40 minutes.
  - ❍ see Cook Book Section - 8.1.2 on page 71.
- ❒ **Replace Reagent Containers** (see Cook Book section “Reagent containers” on page 8-74).
  - ❍ Approx. duration: 5 minutes.
- ❒ **Barcode Maintenance**
  - ❍ All barcodes used with the ML F.A.M.E. should be inspected on a regular basis. It is recommended that a brief check be made during monthly maintenance to ensure all barcodes are clean and in a good physical condition.

    If they require replacement, attach the new barcode label directly over the existing one.

15.1.7 Maintenance Requirements

ATTENTION

The Cold Start Plate must be in the extra slot of the rear tower of incubator module 2 to run weekly maintenance, otherwise the procedure will abort.

15.1.7.1 Cold Start Maintenance Requirements

Before any maintenance procedures can be carried out, the instrument must be initialized, see Reference Guide Section 13.2.1 on page 138.

For a step by step guide to the various maintenance procedures, see Cook Book Section - 8.1.1 on page 70.

An initialization must also be executed if an unrecoverable error occurs in a maintenance procedure.

Specific Items Required for Cold Start:

NOTE
With instruments containing only one washer (16/20 and 24/20), only half of the check plate is filled with fluid during cold start.

Instrument configuration	*Item required*
16/20 and 16/30	Wash fluid container containing minimum 1.5 l of Rinse Solution (deionized water). Wash fluid container containing minimum 1 l NaCl solution deionized water.
24/20 and 24/30	2 wash fluid containers containing minimum 1.5 l of Rinse Solution (deionized water). 2 wash fluid containers containing minimum 1 l NaCl solution deionized water.
All configurations	Cold Start Plate (Barcode: Cold Start 0000) (should already be in the extra slot of incubator 2).

15.1.7.2 Daily Maintenance Requirements

NOTE
If the system is used 24 hours a day, daily maintenance should be carried out at least once a day.

Daily maintenance must be carried out every day before the system is shut down.

For a step by step guide to the various maintenance procedures see Cook Book Section - 8.1.1 on page 70.

Specific Items Required for Daily Maintenance:

Instrument configuration	*Item required*
16/20 and 16/30	Wash fluid container containing minimum 1.5 l of deionized water
24/20 and 24/30	2 wash fluid containers containing minimum 1.5 l of deionized water

15.1.7.3 Weekly Maintenance Requirements

For a step-by-step guide to the various maintenance procedures see Cook Book Section - on page 70.

Specific Items Required for Weekly Maintenance:

Instrument configuration	*Item required*
16/20 and 16/30	Wash fluid container containing minimum 1.5 l *Disinfectant* at 50°C. Wash fluid container containing minimum 1.5 l NaCl solution deionized water. Wash fluid container containing minimum 1.5 l of deionized water.
24/20 and 24/30	2 wash fluid container containing minimum 1.5 l *Disinfectant* at 50°C. 2 wash fluid containers containing minimum 1.5 l NaCl solution deionized water. 2 wash fluid containers containing minimum 1.5 l of deionized water.
All configurations	Cold Start Plate (should already be in extra slot of incubator 2). Spillage Tray.

15.1.7.4 Monthly Maintenance Requirements

For a step-by-step guide to the various maintenance procedures see Cook Book Section - 8.1.1 on page 70.

Specific Items Required for Monthly Maintenance:

Instrument configuration	*Item required*
16/20 and 16/30	Wash fluid container containing minimum 2 l of a suitable disinfectant solution (see section 15.1.2 for recommendations). Wash fluid container containing minimum 2 l NaCl solution deionized water. Wash fluid container containing minimum 1.5 l of deionized water.
24/20 and 24/30	2 wash fluid container containing minimum 2 l of a suitable disinfectant solution (see section 15.1.2 for recommendations). 2 wash fluid containers containing minimum 1.5 l NaCl solution deionized water. 2 wash fluid containers containing minimum 1.5 l of deionized water.
All configurations	Cold Start Plate (should already be in extra slot of incubator 2). Spillage Tray. Possible replacement barcode labels.

15.1.7.5 Cleaning the Washer Manifold

There are two menu options used to aid the removal and reinstallation of the washer manifold. One lowers the manifold for removal, the other raises it back into its rest position after reinstallation. In the 24/20 and 24/30 instrument configurations there are two manifolds to clean.

For a step-by-step guide to the various procedures involved in washer manifold maintenance see Cook Book Section - 8.1.2 on page 71.

Recommended cleaning intervals:

- ❒ Every month (this is done during monthly maintenance).
- ❒ When a manifold needle becomes blocked (an error message is displayed when this happens).

Specific Items Required:

- ❒ Wash fluid container containing deionized water.
- ❒ Manifold cleaning set (see Figure 15.2).
- ❒ Spillage tray (supplied with instrument, see Figure 15.3).
- ❒ Ultrasonic bath (optional).

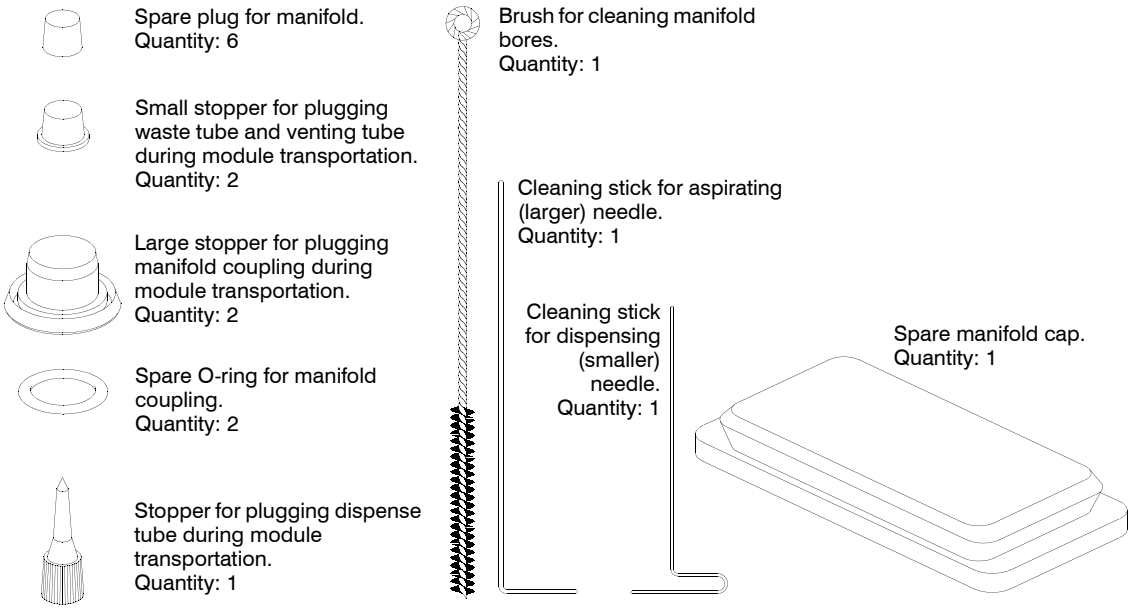

Spare plug for manifold.
Quantity: 6
Small stopper for plugging waste tube and venting tube during module transportation.
Quantity: 2
Large stopper for plugging manifold coupling during module transportation.
Quantity: 2
Spare O-ring for manifold coupling.
Quantity: 2
Stopper for plugging dispense tube during module transportation.
Quantity: 1
Brush for cleaning manifold bores.
Quantity: 1
Cleaning stick for aspirating (larger) needle.
Quantity: 1
Cleaning stick for dispensing (smaller) needle.
Quantity: 1
Spare manifold cap.
Quantity: 1

Figure 15.2 Contents of Manifold Cleaning Set

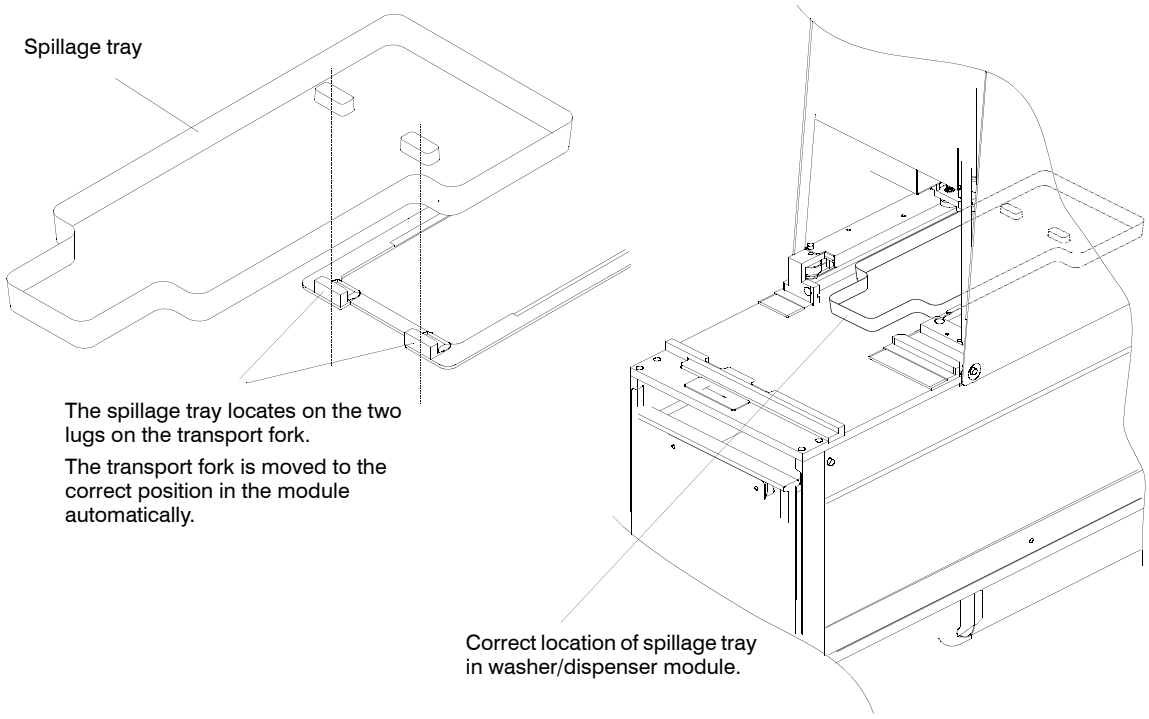

Spillage tray
The spillage tray locates on the two lugs on the transport fork.
The transport fork is moved to the correct position in the module automatically.
Correct location of spillage tray in washer/dispenser module.

Figure 15.3 Spillage Tray and its Position in Module

15.1.8 Washer Decontamination

NOTE
Decontamination takes about 40 minutes.

Recommended interval

❒ Every month

Specific Items Required

Instrument configuration	*Item required*
16/20 and 16/30	Wash fluid container containing minimum 2 l of a suitable disinfectant solution (see section 15.1.2 for recommendations). Wash fluid container with 1.5 l deionized water containing 0.5 g/l NaCl Wash fluid container containing 1.5 l deionized water.

ATTENTION
Empty waste container(s) before starting washer decontamination. Dispose of waste liquid using Good Laboratory Practice.
Wear gloves during the washer decontamination procedure.

ATTENTION
If not working with the waste cap, clamp the waste tubing to prevent liquid spillage.

General Description of Decontamination Procedure

During decontamination the following steps are carried out:

- ❒ The washer(s), all wash channels and all tubings are rinsed with decontamination fluid. When decontaminating with Microlab Detergent and Disinfectant, fill the wash container with 1% solution at 60°C.
- ❒ The waste extraction system is soaked with decontamination fluid for 30 minutes.
- ❒ The washer(s), all wash channels and all tubings are rinsed with 0.5 g/l NaCl and deionized water.
- ❒ Empty external water separator after the washer decontamination is finished.

ATTENTION
Foam may be expelled from the venting tube into the external water separator during the decontamination process.

15.1.9 Incubator Decontamination

Recommended interval:

- ❒ Every month

General Description of Decontamination Procedure

- ❒ This program raises the rear and front incubator towers in turn allowing each slot to be opened and cleaned.

For each bank of towers (front and rear), do the following:

- ❒ Clean each incubator slot with a lint-free cloth soaked in *Microlab™ Disinfectant Spray*.
- ❒ Leave the incubator slot doors open, wait until the slots are dry (typically 30 minutes) and then click on **Continue**.
- ❒ Continue by following the instructions that appear.
- ❒ Complete the procedure by executing an initialization.

ATTENTION
The incubators must be decontaminated at or around ambient temperature since flammable liquids are used.

ATTENTION
Wear gloves when cleaning the incubator slots. They may be contaminated.

Chapter 16 Technical Specifications

Table of Contents

16.1 - General Instrument Specifications....184
16.1.1 - Power Supply....184
16.1.2 - Instrument Dimensions....185
16.1.3 - Instrument Weight (without packaging)....185
16.1.4 - Circuit Breaker Ratings....185
16.1.5 - Operating Environment....186
16.2 - Module Specifications....187
16.2.1 - Entry Module....187
16.2.2 - Incubator Module....187
16.2.3 - Washer/Dispenser Module....188
16.2.4 - End Module....190
16.3 - Barcode Specifications....191
16.3.1 - Plate Barcodes....191
16.3.2 - Reagent Container Barcodes....193
16.4 - PC Requirements....196
16.4.1 - Accessories....196
16.4.2 - Optional PC Requirements....196
16.4.3 - User Software Specifications....197

16.1 General Instrument Specifications

16.1.1 Power Supply

Electrical Supply:	115/230 V, 60/50 Hz, 10/5 A
Details: **- Mains Voltage:** **- Mains Frequency:** **- Power Consumtion:**	 90 - 132 V / 180 - 264 V 45 - 66 Hz ≤ 900 VA, 675 W
Installation Category:	II *(according to IEC 1010-1)*
Pollution Degree:	2

Power Supply Interruption

NOTE
This applies only to the instrument. The computer specifications may vary.

The instrument will run undisturbed during power supply interruptions from the nominal mains voltage (± 15%) of less than 100 ms.

For interruptions exceeding this limit, a UPS (uninterruptable power supply) is recommended.

Recommendations for UPS

To provide disturbance-free service with all mains electricity supplies, it is recommended to use the instrument and computer with an uninterruptable power supply (UPS). A UPS will provide power to the system for power supply interruptions.

The UPS is used as a battery during power supply interruptions. The UPS status information currently cannot be monitored by the user software.

The software supplied with the UPS should be installed on the PC and when “battery low” is indicated the system should be shut down.

One of the following uninterruptable power supplies is recommended:

Manufacturer:	**Best**	**Fiskars**	**Siemens**
Headquarters:	Best Power Technology Inc. P.O. Box 280 Necedah Wisconsin 54646 U.S.A.	Fiskars Power Systems SF-02921 Espoo Finland	Siemens AG Postfach 3240 D-8520 Erlangen Germany
Output Power:	2000 VA / 1500 W	2000 VA / 1400 W	2000 VA / 1400 W
Backup Power Time:	10 min @ full power 30 min @ half power	10 min @ full power 30 min @ half power	10 min @ full power 20 min @ half power
Overload Capacity:	125% - 10 min 150% - 1 min	125% - 10 min 150% - 1 sec	140% - 25 sec
Weight	54.5 kg	68 kg	45 kg
Dimensions (mm):	445 x 205 x 485	440 x 190 x 490	464 x 193 x464
RS-232 Interface:	yes	yes	yes
Software Support:	yes	yes	yes

16.1.2 Instrument Dimensions

	Length (l)	**Breadth (b)**	**Height (h)**
16/20:	1260 mm (4’ 1”)	680 mm (2’ 3”)	810 mm (2’ 8”)
16/30:	1470 mm (4’ 10”)	680 mm (2’ 3”)	810 mm (2’ 8”)
24/20:	1470 mm (4’ 10”)	680 mm (2’ 3”)	810 mm (2’ 8”)
24/30:	1680 mm (5’ 6”)	680 mm (2’ 3”)	810 mm (2’ 8”)

16.1.3 Instrument Weight (without packaging)

16/20:	220 kg (485 lbs.)
16/30:	250 kg (550 lbs.)
24/20:	272.5 kg (600 lbs.)
24/30:	302.5 kg (666 lbs.)

16.1.4 Circuit Breaker Ratings

Primary Circuit Breakers (Mains)

Four 5 A thermal circuit breakers. Both live and neutral lines protected.

All circuit breakers are located behind the panel on the left side of the instrument, near the mains switch.

16.1.5 Operating Environment

Operating temperature range:	+15 to +35 °C
Humidity:	up to 85%
Indoor use only	-
Altitude:	2000m max.

16.1.6 Compliance with EU-Directives

The ML F.A.M.E. is in conformity with the requirements of the EMC directive (EN 50081-1 and EN 50082-2) and low voltage directive (EN 61010-1) of the European Community (CE label). Please note that this instrument has been designed and tested to meet the requirements of residential environments.

16.2 Module Specifications

16.2.1 Entry Module

16.2.1.1 Entry Stack

Capacity:	Up to 4 plates
MTP identification:	by barcode

16.2.1.2 Incubator Towers

Front Tower:	5 slots ambient temperature
Rear Tower:	5 individually temperature-controlled slots. One temperature can be assigned per tower
Temperature range:	ambient to 45 °C (active control starting at 5 °C above ambient)
In steps of:	1 °C

16.2.2 Incubator Module

16.2.2.1 Incubator Towers

Front Tower:	5 individually temperature-controlled slots. One temperature can be assigned per tower
Temperature range:	ambient to 70 °C (active control starting at 5 °C above ambient)
In steps of:	1 °C
Rear Tower:	Identical to front tower
Maximum temperature difference between front and rear towers:	25 °C

Incubator Slot Temperature Variation (temperature-controlled incubation)

Temperature	Variation at target temperature
Up to 45 °C	≤ ± 1 °C[a]
46 - 70 °C	≤ ± 2 °C

a. This specification is valid under the following test conditions:
Type of MTP: Incubator Check Plate
Test Method: Verification
Test Temperature:37°C

16.2.3 Washer/Dispenser Module

16.2.3.1 Washer

24 channel manifold (8 × 3 array) with liquid level detection on each needle.

Wash volume: **In steps of:**	50 - 400 µl 10 µl
Residual volume after washing:	Mean ≤ 10 µl/well[a] Typically ≤ 5 µl/well[a]
Number of wash cycles:	1 - 9
Wash modes:	Dispense only Strip Wash Plate Wash
Soak time: **Plate Wash:** **Strip Wash:** **Wash options:**	 20 - 300 s 0 - 60 s Continuous wash Bottom wash Bottom sweep
Number of wash containers:	3 per washer
Number of rinse containers:	1 per washer
Wash/Rinse container capacity:	3 litres
Waste container capacity:	10 litres, LLD detection when using waste cap (exchangeable during operation).
External water separator capacity:	4 litres

a. This specification is valid under the following test conditions:
Type of MTP: Check Plate
Test Method: Photometric
Test Temperature:18 - 26°C
Test Medium: Aqueous dye solution

16.2.3.2 Dispenser

Reagent Container Carousel

Capacity:	8 reagent containers

Reagent Container System

Volume of syringe:	20 ml
Dispense volume per well:	20 - 200 µl[a]
In steps of:	5 µl
Reagent container capacity:	100 ml approx.
Reagent identification:	By barcode

a. Accuracy and precision not specified for volume ranges of 20 - 45 µl.

Dispensing Precision/Accuracy

Volume (µl)	**Precision (≤% CV)**		**Accuracy (≤ ±%)**	
50	1.5[a]	5[b]	5[a]	5[b]
100	1.5[a]	5[b]	5[a]	5[b]
200	1.0[a]	5[b]	2.5[a]	5[b]

a. This specification is valid under the following test conditions:
Test Method: Gravimetric
Test Temperature:18 - 26 °C
Test Medium: Deionized water containing 0.05% NaCl.
b. This specification is valid under the following test conditions:
Test Method: Photometric
Test Temperature:18 - 26 °C
Test Medium: Washer/Dispenser verification kit check solutions.

16.2.3.3 Mixer

See section 16.2.4.2 on page 16-190.

16.2.4 End Module

16.2.4.1 Photometer

Number of measuring channels:	8 (8 wells can be measured simultaneously)
Number of reference channels:	1
Filters supplied as standard with instrument: (5 total)	340 nm 405 nm 450 nm 492 nm 620 nm
Maximum possible number of filters in instrument:	8
Wavelength range of additional filters:	340 - 750 nm
Linear Measurement range 400 - 750 nm:	0.00 - 2.5 OD
Linear Measurement range 340 - 400 nm:	0.00 - 2.0 OD
Indication range:	0.0 - 2.999 OD
Linearity above 400 nm **0.0 - 1.2 OD** **1.2 - 2.5 OD**	 $\leq \pm$ 0.005 OD or $\leq \pm$ 0.5%, whichever is greater $\leq \pm$ 0.75%
Linearity at 340 nm **0.5 - 2.0 OD**	 $\leq \pm$ 2.5%
Precision (variation over plate of a pooled material) above 400 nm in range 0 - 1.5 OD	$\leq \pm$ 2.0% or $\leq$ 0.005 OD, whichever is greater.
Reproducibility (repeat reads of same plate) above 400 nm and 1.0 OD	$\leq \pm$ 0.3%

16.2.4.2 Mixer

Mix mode:	Lengthwise shaking of plate with 3 different intensities and programmable mix time.

16.2.4.3 Dispenser

See section 16.2.3 on page 16-188.

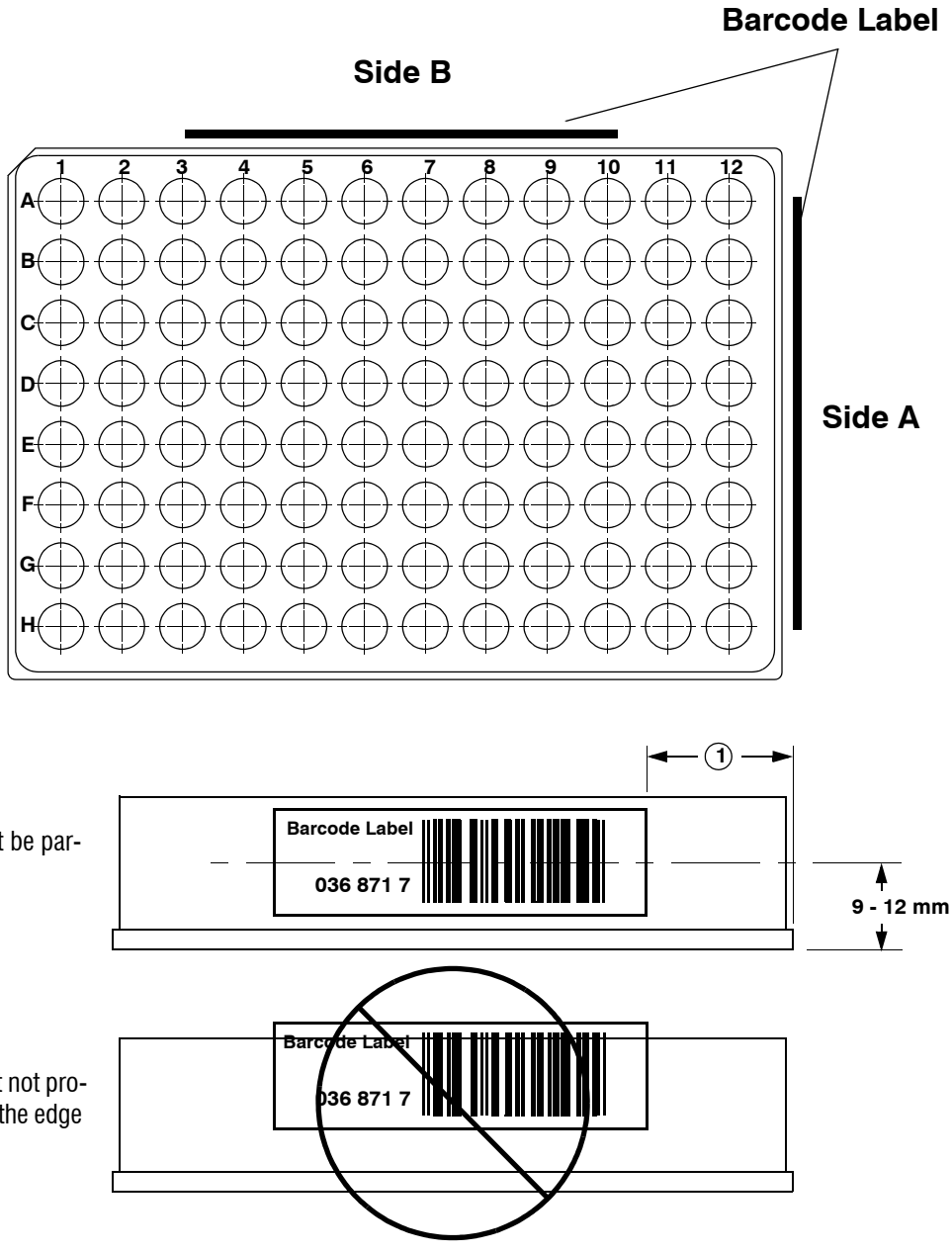
16.2.4.4 Exit Stack

Capacity:	Approx. 10 plates (dependent on plate thickness).

16.3 Barcode Specifications

16.3.1 Plate Barcodes

The plate barcode must fit on side A or side B of the plate as shown in Figure 16.1 below. The barcode label must meet the following specifications:



NOTE
The barcode label must be parallel to edge of plate.

NOTE
The barcode label must not protrude above or below the edge of the plate.

Figure 16.1 Plate Barcode Positioning

Horizontal Position (1)

The label can be positioned anywhere along the whole length of side A or side B. The optimum position is in the middle, a minimum distance of 10 mm from both edges is required. The label must be parallel to the plate edge.

Label Dimensions

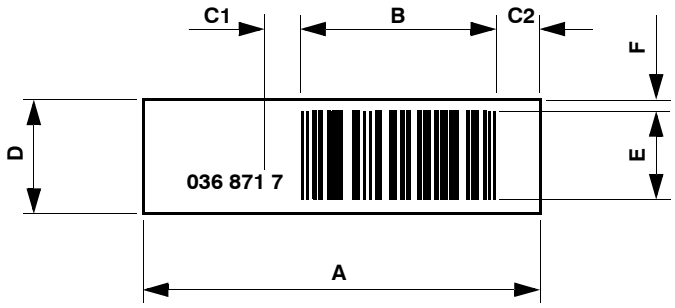


Figure 16.2 Barcode Label Dimensions

Dimension		Min	Max
A	Label length	-	66 mm
B	Code length	-	60 mm
C1,C2	Quiet zone	3 mm	-
D	Label width	7 mm	-
E	Code width	7 mm	-
F	Distance from code to label edge	-	1 mm

Print Quality

ATTENTION
The label must perfectly adhere to the surface during the whole of its working life.

The barcode print must be of a high quality. Offset, typographic, intaglio and flexographic printing are suitable.

Mechanical dot matrix and thermomatrix printing are not suitable. The surface may be untreated, sealed or plastic-covered.

Barcode Symbology

The following barcodes are recommended for use with the bar-code reader:

- ❒ Code 39 with or without check characters
- ❒ Interleaved 2 of 5 with or without check characters
- ❒ Codabar
- ❒ Code 128
- ❒ UPC A/E
- ❒ JAN/EAN 8

Length of Information

Maximum 32 characters excluding start, stop and check characters, depending on the code length (see label dimensions).

Print Contrast Signal

Minimum contrast between bars and spaces (PCS):	80% (at 632.8 nm).

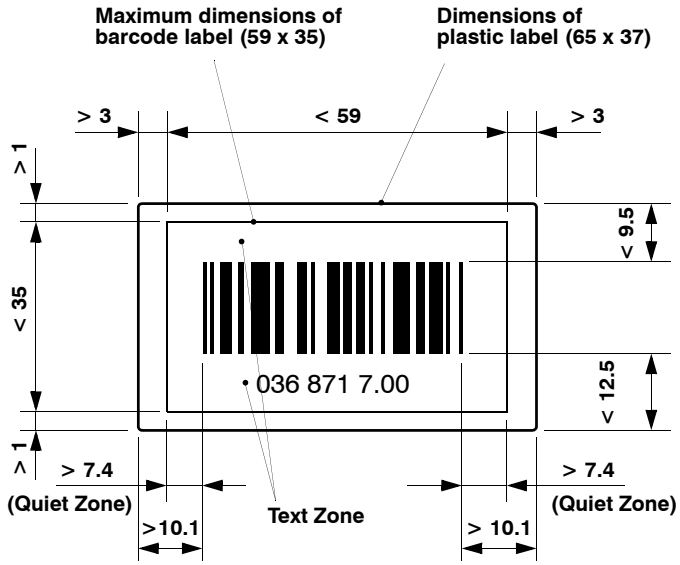
Code Density, Tolerance

Minimum module width including print tolerances:	0.0065” (0.1651 mm)

16.3.2 Reagent Container Barcodes

A set of 52 plastic barcode labels is provided with the instrument. User-defined barcodes must fit on the back of these barcode labels and must meet the following specifications.

Label Dimensions



Dimensions in mm

Figure 16.3 Reagent Container Barcode Label Dimensions

Print Quality

Same as plate barcodes, see page - 192.

Print Contrast Signal

Same as plate barcodes, see page - 192.

Barcode Symbology

Same as plate barcodes, see page - 192.

Length of Information

Same as plate barcodes, see page - 192.

Code Density, Tolerance

Minimum module width including print tolerances:	0.01” (0.254 mm)

Restrictions of Barcode Content

The last three characters of any reagent barcode are reserved for instrument control and must always be “.00”; the other, up to 29 characters are freely definable.

NOTE
The barcodes REAGENT 46.00, REAGENT 47.00 and REAGENT 48.00 are reserved for service and maintenance purposes. The barcodes CHECK SOLUTION A, CHECK SOLUTION B, CHECK SOLUTION C and CHECK SOLUTION D are also reserved. This leaves 45 different barcodes for daily routine use.

Content of Labels Provided with Instrument

The barcode labels supplied with the instrument have the following structure:

REAGENT XX.00

where XX ranges from 01 to 48.

Barcode Positioning

Figure 16.4 shows the positioning of the barcode on the reagent container.

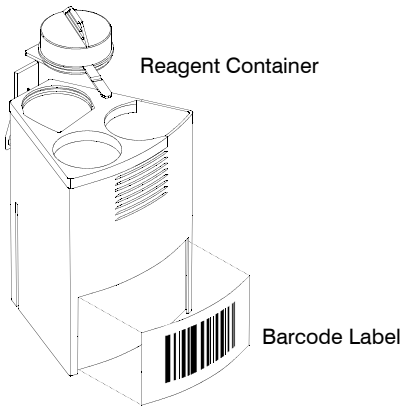


Figure 16.4 Position of Barcode on Reagent Container

Vertical Position

The vertical position should be such that the centre of the barcode is 20 mm from the bottom of the reagent container.

Horizontal Position

The horizontal position should be such that the barcode is centered on the reagent container.

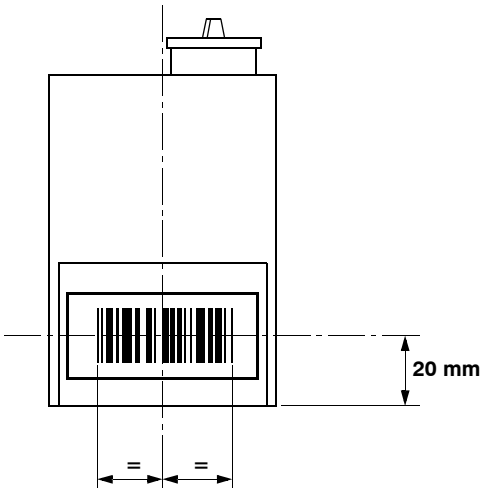


Figure 16.5 Optimum Position of Barcode on Reagent Container

16.3.3 Wash Fluid Container and External Pump Station Barcodes

Barcodes must be attached to the external pump station and the wash fluid container as per the picture below.

Figure 16.6 Wash fluid container and external pump station - Barcode label position

16.4 PC Requirements

NOTE
The PC must be OS/2 compatible. Ask the manufacturer/supplier for confirmation.

The minimum requirements for the PC (i.e. for a stand-alone system without connection to Microlab AT or LAN) are given below.

Microprocessor type:	Intel Pentium 100 MHz
Hard disk:	1.0 GB
RAM:	48 MB
Floppy disk drive:	1 drive ($3^1/_2$")
Interface ports:	1 serial port (RS232C) for connection to the Summit Processor 1 mouse port (either RS232C or dedicated mouse port) 1 parallel port for the printer
VGA or SVGA monitor:	Colour monitor supported by OS/2
Keyboard:	Any keyboard supported by OS/2
Mouse:	Any mouse supported by OS/2
Operating system: Database:	IBM OS/2 V4.0 WARP IBM DB2/2 V2.10

16.4.1 Accessories

General:	Barcode scanner - to be connected in parallel to the keyboard - possible to program pre- and postamble

16.4.2 Optional PC Requirements

Interfaces:	LAN interface card or serial port for connection to host computer. 1 serial port (RS232C) for use with UPS (Uninterruptable Power Supply).
Additional computers:	Host computer for archiving results.
Printer:	HP Laserjet 5 L and Epson LX850 have been tested and deemed as compatible with the ML F.A.M.E. software.

16.4.3 User Software Specifications

Maximum number of methods storable in database:	100 [a]
Maximum number of test results storable in database:	700 [a]
Maximum number of stacks:	50 [a]
Maximum number of stacks in a work list:	100
Maximum number of work lists:	30 [a]

a. Depends on amount of free space on hard disk.

16.4.4 Data Output Protocol

Result files are created and exported in an ASTM protocol format see Reference Guide Section 13.2.5 on page 142 and see Reference Guide Section 12.2.5 on page 134. Detailed information about the data output protocol is available on request.

Chapter 17 Troubleshooting & Error Handling

Table of Contents

17.1 - Error Handling 200
17.1.1 - Example Error-Handling Message Dialog Boxes 200
17.1.2 - Warning Dialog Boxes 200
17.1.3 - Handling of System Deadlocks 200
17.1.4 - User Actions which Can Adversely Affect a Run 201
17.1.5 - What to Do if an Error Cannot Be Rectified 203
17.1.6 - Aborting a Test Run 203
17.1.7 - Tools and Their Usage During Error Handling 203
17.1.8 - Collision-Free Positions 205
17.1.9 - Locking of Instrument Functions 207
17.1.10 - Unlocking Instrument Functions 208
17.2 - Troubleshooting Tables 209
17.2.1 - User Software, OS/2 and PC Related Problems 209
17.2.2 - Module Specific Problems 209
17.3 - Instrument Auto Adjustment 212

17.1 Error Handling

The user software contains error-handling procedures which enable problems to be rectified without necessarily aborting plates.

If the user software encounters a problem, it tries to rectify the problem in one of the following ways:

❒ Automatically without operator intervention.

❒ By issuing instructions to the operator via an error-handling message dialog. If the instructions are followed, the error can usually be rectified.

ATTENTION
Error handling instructions should be carried out as quickly as possible to prevent plates from being aborted.

17.1.1 Example Error-Handling Message Dialog Boxes

Typically, error dialogs contain the following items:

❒ Error ID at top of dialog.

❒ Description of the error.

❒ The test (plate) affected.

❒ The actions required of the operator to rectify the error.

❒ A number of buttons allowing the operator to choose how to continue.

17.1.2 Warning Dialog Boxes

NOTE
Warning dialogs have no associated ID number.

Warning Dialog Boxes appear before an error occurs. If the instructions given are carried out, the error will be prevented.

17.1.3 Handling of System Deadlocks

If a system deadlock (“System error Detected”) occurs during a run and plates are still in the instrument or syringes are held in the dispenser head, the recovery procedure is as follows:

1 Try (if possible) to abort the run by selecting from the Abort menu in the Work List Manager Window either Test or Run. This should stop all test processing.
2 Switch off the instrument.
3 Shut down the ML F.A.M.E. software.
4 Shut down the operating system (OS/2).
5 Restart the instrument, the operating system and user software in this order.

All syringes will then be parked and all plates in the instrument will be transported to the exit stack.Check if the lens block of the photometer is clean before the instrument is re-used.

17.1.4 User Actions which Can Adversely Affect a Run

17.1.4.1 Switching the Instrument On/Off

ATTENTION
The following notes should be read carefully. They contain important information which can reduce the occurrence of errors in the system.

The instrument should not be switched off during a run.

If the instrument is switched off, wait at least 20 seconds before switching it on again.

If the instrument is switched off and then immediately on again, it is possible that only the message relating to the latest change of instrument state will be displayed on the computer screen (i.e. the message that the instrument has been switched on during a run and not off).

17.1.4.2 Shutting Down the User Software/PC

The PC should not be switched off during a run or while the user software is running. The proper OS/2 shutdown procedure should always be followed.

17.1.4.3 Pressing the Pause Button

The pause button is located at the bottom of the right hand side of the ML F.A.M.E., see Figure 1.2. Pressing the pause button halts all actions being carried out on the instrument.

After the pause button has been pressed, a message dialog appears on the computer screen, containing a button allowing instrument operations to be continued.

Pressing the pause button can cause plates to be aborted.

17.1.4.4 Opening the Transparent Cover

ATTENTION
When the transparent cover is opened, the main shuttle stops (i.e. the part that moves plates from module to module) but all functions within modules continue.

A sensor detects when the transparent cover is open.

If the transparent cover is opened during a run, the schedule may be lost and plates may be aborted.

The transparent cover should only be opened when instructed during maintenance and error handling.

17.1.4.5 Pressing the Load Button

When pressed, the load button initiates the loading of plates into the instrument.

17.1.4.6 Opening the Reagent Drawers

ATTENTION

During a run, the reagent drawers should only be opened to load and remove reagent containers or carousels when instructed by the ML F.A.M.E. software or when instructed during an error handling procedure and should not be opened for longer than absolutely necessary.

There are two switches associated with a reagent drawer.

An internal switch detects when a reagent drawer is open and prevents the dispenser from accessing the reagent carousel.

A second switch located behind the drawer handle detects when the operator attempts to open the drawer.

Do not open drawers while the reagent rotor is rotating.

If a reagent drawer is left open, its associated dispenser will be blocked which may cause tests to be aborted.

If a drawer is opened and closed, all reagent containers will be reidentified.

17.1.4.7 Wash/Rinse Solution Loading

Each wash channel has a switch that detects low fluid level in the wash fluid container.

There is also a sensor that detects the position of the fluid connector, i.e. whether it is in the horizontal (wash) position or the vertical (rinse) position.

If there is insufficient fluid in a wash fluid container or if the fluid connector is in the wrong position, the washer cannot operate. A message will appear on the computer screen informing the ML F.A.M.E. operator of this. If the appropriate action is not taken in time, the plate to be washed will be aborted.

The rinse container(s) should be filled up before the start of a run.

17.1.4.8 Waste Cap

The waste cap contains a liquid level sensor that detects when the waste container is nearly full. A warning dialog then appears on the computer screen requesting it to be emptied.

It is recommend to emptying the waste container(s) before each test run or at latest when requested by the user software. If the waste container is not changed as requested, the washer will be locked and plates may be aborted.

17.1.4.9 Removing Plates from Instrument

A sensor detects when the exit stack is nearly full (6 - 7 plates (depends on plate height)) and also when it is completely full (10 - 11 plates).

Plates should be removed from the exit stack before it becomes full, i.e. when instructed in the action list. If the exit stack remains full, it will be blocked and as a result, may cause tests to be aborted.

17.1.5 What to Do if an Error Cannot Be Rectified

NOTE
Trace files can be edited using any ASCII-text editor. The appropriate part of the trace can then be extracted, saved and printed out.

If an error is encountered with the system which cannot be rectified by the ML F.A.M.E. operator, print out the system and test traces as applicable, fill in an incident report form and send (fax) it with the traces to HAMILTON (See Cook Book page - 60 for information on printing traces).

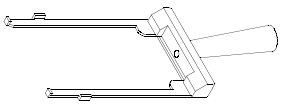
17.1.6 Aborting a Test Run

Any active error handling must first be completed before a test run can be aborted, i.e any instructions in an error dialog must first be carried out and the dialog then closed.

17.1.7 Tools and Their Usage During Error Handling

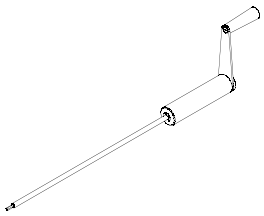
The ML F.A.M.E. comes supplied with a number of tools for use when serious mechanical/electrical failures occur.

17.1.7.1 Plate Fork



The plate fork is used to manually remove plates from incubator slots. It should only be used under fatal error conditions when plates cannot be removed automatically by the system, e.g. when an incubator tower motor drive fails.

17.1.7.2 Height Mover Tool



The height mover tool manually raises and lowers the following:

- ❒ Incubator towers
- ❒ Dispensers
- ❒ Entry lift

Figure 17.1 shows where the height mover tool should be inserted to move these items. Figure 17.2 shows how and where to use this tool. The example given is for the entry module front incubator tower. The procedure is identical for the other items.

NOTE
Use the tools only when instructed via an error-handling dialog or when the instrument is switched off.

The height mover tool should only be used under fatal error conditions when such items cannot be raised and lowered automatically by the system, e.g. due to a motor drive failure or when explicitly instructed by the user software.

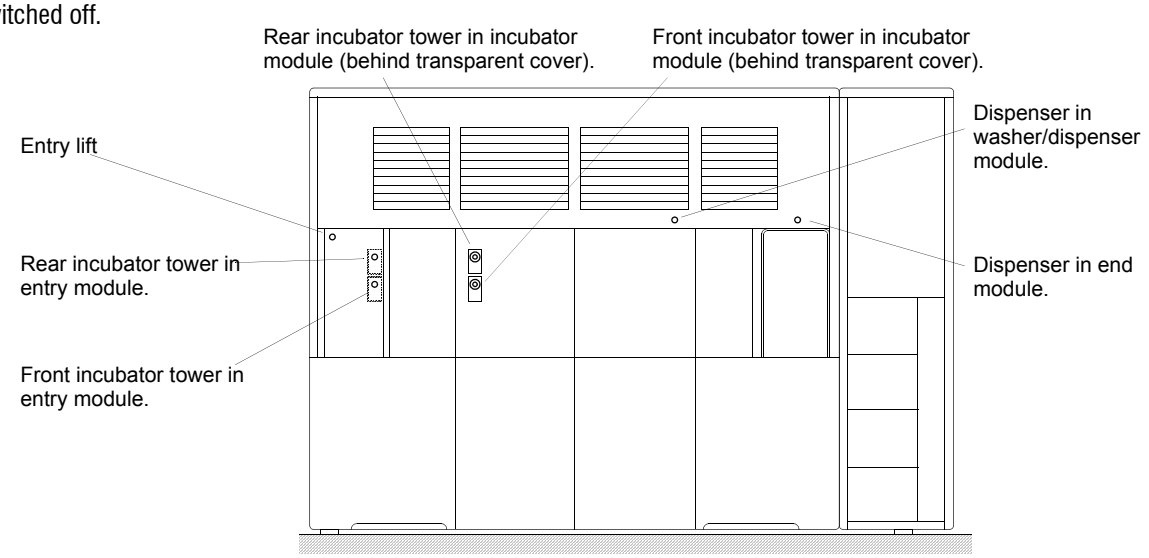
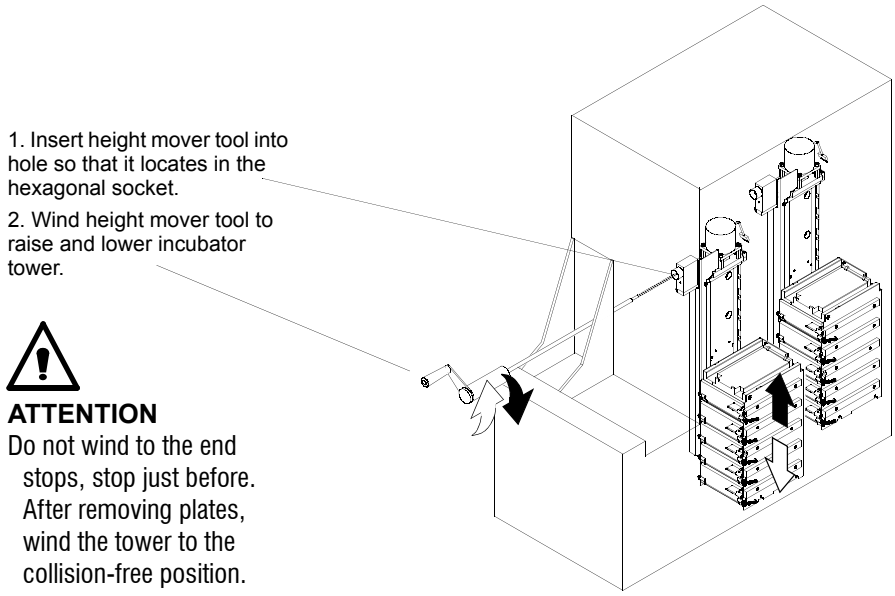

Rear incubator tower in incubator module (behind transparent cover).
Front incubator tower in incubator module (behind transparent cover).
Entry lift
Dispenser in washer/dispenser module.
Rear incubator tower in entry module.
Dispenser in end module.
Front incubator tower in entry module.

Figure 17.1 Location of Height Mover Tool Insertion Points


1. Insert height mover tool into hole so that it locates in the hexagonal socket.
2. Wind height mover tool to raise and lower incubator tower.

ATTENTION
Do not wind to the end stops, stop just before. After removing plates, wind the tower to the collision-free position.

Figure 17.2 Use of Height Mover Tool

17.1.8 Collision-Free Positions

ATTENTION
Do not use excessive force to move mechanical parts.

Under certain error conditions the ML F.A.M.E. operator may be asked (via an error dialog) to manually move an instrument module or function into a “collision-free position”. It may also be necessary to manually remove a plate from the instrument in this situation. The following sections explain what is meant by a collision-free position.

17.1.8.1 Entry Module

- ❒ Module transport in main shuttle position (Figure 17.4), i.e. fork in outermost position (move by hand).
- ❒ Front incubator tower in its lowest position (use height mover tool).
- ❒ Entry lift in its highest position (use height mover tool).

17.1.8.2 Incubator Module

- ❒ Module transport in main shuttle position (Figure 17.4), i.e. fork in outermost position (move by hand).
- ❒ Front incubator tower in its lowest position (use height mover tool).

17.1.8.3 Dispenser

- ❒ Module transport inside module just clear of main shuttle (Figure 17.4)(move by hand).

❒ Dispenser head in uppermost position in drop position (Figure 17.3). Move the dispenser head up and down using the height mover tool. Move the dispenser head from left to right by hand.

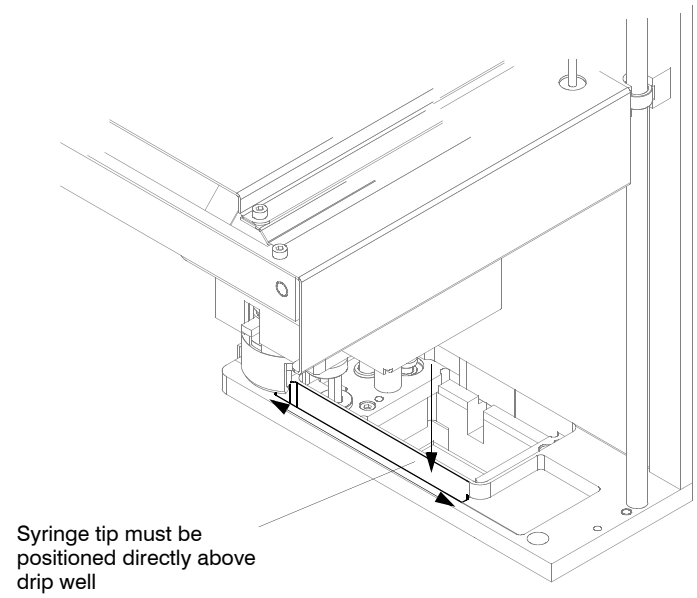


Figure 17.3 Drop Position of Dispenser Head

17.1.8.4 Washer

❒ Manifold in uppermost position (move by hand. Requires considerable force).

17.1.8.5 Photometer

Not applicable.

17.1.8.6 Transport System

MTP transporter away from entry lift (move by hand) (Figure 17.4). Exit lift in its lowest position (move by hand. Apply pressure at the inner-most end of lift, near the spindle).

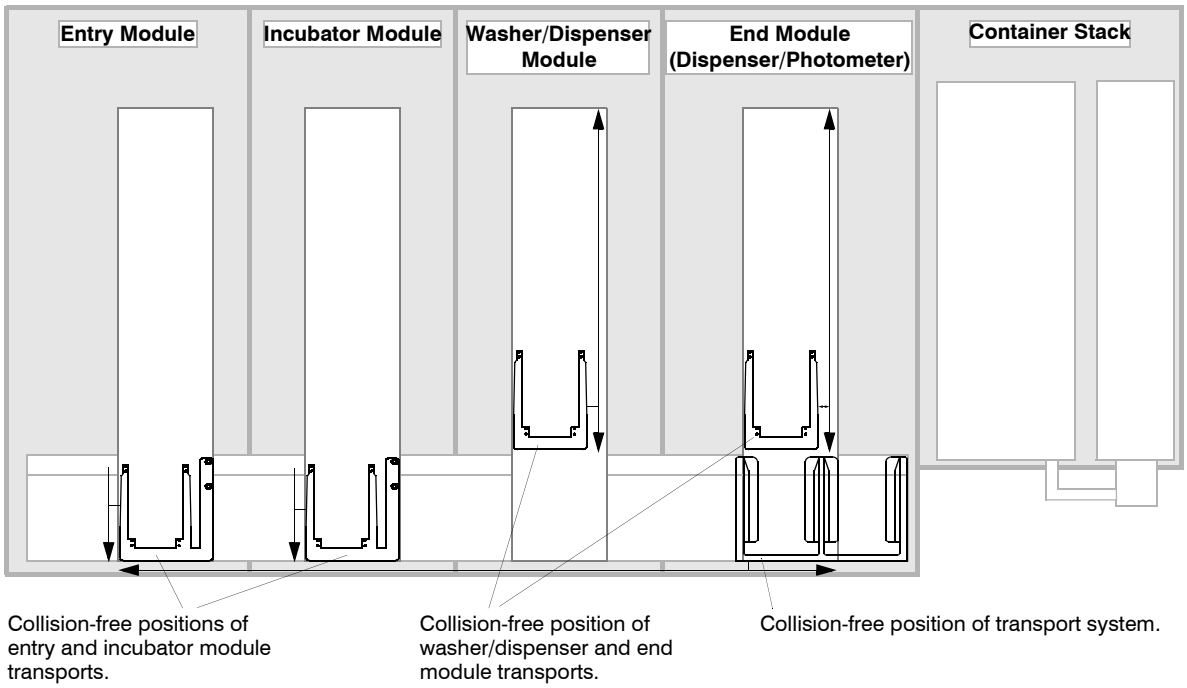

Entry Module
Incubator Module
Washer/Dispenser Module
End Module (Dispenser/Photometer)
Container Stack
Collision-free positions of entry and incubator module transports.
Collision-free position of washer/dispenser and end module transports.
Collision-free position of transport system.
Diagram not to scale.

Figure 17.4 Collision-Free Positions of Module Transports and Transport System

17.1.9 Locking of Instrument Functions

Instrument functions can be locked in two different ways:

- ❒ By the operator if not all functions are needed for a run. This should be avoided if possible as locking a function changes the throughput of the instrument and under certain circumstances it will not be possible to start a test run or continue with an existing test run.

- ❒ When the user software detects a fault in an instrument function. If the user software locks an instrument function during a run, a message dialog appears on the computer screen informing the ML F.A.M.E. operator of this.

17.1.10 Unlocking Instrument Functions

Instrument functions can be unlocked in two different ways:

- ❒ By the operator (see Cook Book Section - 6.1.1 on page 64). This should be done when a fault with a function has been rectified. Plates requiring this function can then be processed. If the fault persists, the function will be locked again.
- ❒ When the instrument is initialized. In this case, all correctly functioning instrument functions will be unlocked.

17.2 Troubleshooting Tables

The following troubleshooting tables may help to remedy certain problems which may be encounter when using the system.

17.2.1 User Software, OS/2 and PC Related Problems

Symptom	Possible Cause	Corrective Action
PC / OS/2 does not boot.	Non-system disk in $3^1/_2$" drive of PC.	Remove disk from $3^1/_2$" drive of PC and re-boot.
User software does not start up.	PC was not shut down after user software installation.	Shut down and re-boot PC and try starting user software again.
Cannot get connection to instrument.	Computer cable connected to wrong PC serial port or not connected at all.	Check that computer cable is connected to instrument and to correct PC serial port.
	Computer cable faulty.	Check continuity of computer cable and renew if necessary.
Unable to print to the OS/2 default printer.	Printer not connected to LPT1: parallel port.	Check printer connection.
	Printer off line.	Check that printer is on line.
	Physical name not correct.	Check in device presettings that physical name is correct.

17.2.2 Module Specific Problems

Below is a description of some possible problems relating to individual ML F.A.M.E. modules.

17.2.2.1 Washer Problems

Symptom	Possible Cause	Corrective Action
Plates are not washed at all.	External pump station tubings incorrectly connected.	Check for correct connection of external pump station tubing.
Blocked aspirating needle.	An aspirating needle in the manifold is blocked. Aspirating needles not bevelled (old manifold). Dripping from dispensing needles (valve by manifold not liquid tight).	Carry out daily maintenance. Clean manifold. Renew Manifold. Call service technician.
Blocked dispensing needle.	A dispensing needle in the manifold is blocked (crystallization). No wash fluid (air dispensed). Dispense tubing kinked. MTP not in washer/dispenser module. Sensor PCB is wet or dirty.	Carry out daily maintenance. Clean manifold. Refill wash fluid container. Ensure that dispense tubing is not kinked. Clean sensor PCB (PCB under MTP).
Improper wash liquid dispensing. Overfilling of wells during washing.	Fluid connector switched during wash procedure. Insufficient wash fluid. Incorrect calibration of module transport (dispensing needles dispensing next to wells). Incorrect calibration of washer Z-drive.	Carry out daily maintenance. Clean manifold. Refill appropriate wash fluid container. Call service technician. Call service technician.
Vacuum pump overload.	Tubing kinked. Waste cap or substitute plug not connected.	Check tubings. Check that waste cap plug or substitute plug is connected to instrument. If waste cap is used, check that it is on waste container.
Waste container full.	 Dirty sensor rods.	Empty waste container. Clean sensor rods.
Waste cap not on waste container.	Electrical problems. Substitute plug not inserted.	Place waste cap on waste container immediately (otherwise plates will be aborted).
Wash container almost empty.		Refill when green lamp is lit.
Error 342, Wash shell overflow.	Dirty manifold.	Clean manifold.

17.2.2.2 Dispenser Problems

Symptom	Possible Cause	Corrective Action
Insufficient reagent or defective syringe.	Not sufficient reagent loaded. Bad syringe maintenance.	Renew syringe.
Dispensing failed due to air gap/ foam.	Defective syringe.	Renew syringe. After next test step (incubate), check visually if all wells have been filled with reagent. Retest samples. Insert test trace message.
Reagent rotor step lost.	Reagent carousel dirty.	Clean reagent carousel.
Dispenser plunger drive step lost.	Defective syringe. Plunger drive faulty.	Renew syringe. Execute Init/Cold Start. If problem persists, call service technician.
X-direction step lost.	Mechanical problem.	If problem persists, call service technician.
Z-direction step lost.	Mechanical problem.	See section 17.1.8. Execute Init/Cold Start.

General: If there are problems in the end module with dispenser, check if the lens block of the photometer is clean.

17.2.2.3 Incubator Problems

Error Message/Problem	Possible Cause	Corrective Action
Incubator temperatures too high.	Device presettings (incubator temperatures) changed.	Switch off instrument, open incubator slots, check device presettings, shut down user software, wait approx. 15 minutes.
Incubator slots locked.	Heating defect. Temperature too high from previous run.	Call service technician. Wait until slots have cooled down, then restart system.
Temperature out of range.	Room temperature outside of operating range for instrument (see specifications).	Lower room temperature (air conditioning).

17.2.2.4 Photometer Problems

Symptom	Possible Cause	Corrective Action
Module transport of end module locked or general photometer error.	Dirty lens block. Barcode labels blocking out photometer. Bottom of plate wet. Module transport dirty.	Clean photometer area. Check that barcode labels are correctly affixed to plates. Dry bottom of plate and photometer area. Clean module transport.
Photometer measurement aborted due to error.	Filter case drive jamming.	If error persists, call service technician.

17.3 Instrument Auto Adjustment

Some errors can be rectified by adjusting the instrument. An adjustment should only be done by a service technician.

Appendix 1 Error & Trace Codes Messages

Table of Contents

A1.1 - Error Messages Introduction 214
A1.1.1 - Explanation of Formatted Strings 214
A1.1.2 - General Errors 215
A1.1.3 - Dispenser Errors 219
A1.1.4 - Incubator Errors 222
A1.1.5 - Washer Errors.....224
A1.2 - Trace Messages.....226
A1.2.1 - Explanation of Trace Codes.....226
A1.2.2 - Test-Trace Messages.....226
A1.2.3 - Well-Trace Messages 235

A1.1 Error Messages Introduction

The tables in this section list the errors and warnings that may occur while running the instrument. These have an Error ID and then a description of the actual error then. This is given as a reference

A1.1.1 Explanation of Formatted Strings

Some formatted text strings may appear in some messages in the tables. These are explained below.

%s-In the actual error dialog, these characters will be replaced by a text string.

%d-In the actual error dialog, these characters will be replaced by a decimal integer.

%.3-In the actual error dialog, these characters will be replaced by a real number with three digits after the radix.

For example, the message:

Insufficient unstable Reagent.

Replace Container with Barcode ‘%s’ at rotor position %d immediately and close Reagent Drawer. %.3f ml required for next dispense. Pressing Not OK will abort Plate.

might appear on the screen as:

Insufficient unstable Reagent.

Replace Container with Barcode ‘REAGENT 23.00’ at rotor position 3 immediately and close Reagent Drawer. 19.950 ml required for next dispense. Pressing Not OK will abort Plate.

A1.1.2 General Errors

DIALOG ID	MESSAGE
RAD500_1	Communication to the instrument failed. Please switch on instrument again or verify connection cable.
RAD501_1	Cannot get connection to the instrument. Please switch on instrument or verify connection cable.
RAD503_1	Cannot get connection to the instrument. Module(s) are not connected or are in download mode. Call a service-technician.
RAD510_1	System time was manipulated! This session must terminate. Please contact your dealer!
RAD511_1	Cannot open device to selected instrument. The device is possibly already in use (i.e. serial port in use)! This session must terminate.
RAD512_1	Could not execute time synchronize. Call a service technician.
TRP100_1	Could not pre-initialize the Exit Lift. Move the Exit Lift manually into a collision-free position. Press OK if manual intervention was successful, else press Ignore.
TRP110_1	Could not initialize the Exit Lift. Move the Exit Lift manually into a collision-free position. Press OK if manual intervention was successful, else press Ignore.
TRP120_1	Could not initialize the Main Shuttle. Move the Main Shuttle manually into a collision-free position. Press OK if manual intervention was successful, else press Ignore.
TRP130_1	Could not calibrate the Plate Detection Sensor for full Exit Stack. Check whether space between Plate Sensors of the Exit Stack is blocked. Press OK if manual intervention was successful, else press Ignore.
TRP140_1	Could not calibrate the Plate Detection Sensor for manipulation platform on Exit Stack. Check whether space between Plate Sensors of the Exit Stack is blocked. Press OK if manual intervention was successful, else press Ignore.
TRP300_1	Main Shuttle step lost. Could not transport Main Shuttle to target position. Move the Main Shuttle manually to a collision-free position. Press OK if manual intervention was successful, else press Ignore.
TRP310_1	Exit Lift step lost. Could not transport Exit Lift to target position. Move the Exit Lift manually into a collision-free position. Press OK if manual intervention was successful, else press Ignore.
TRP320_1	Exit Stack error. Could not deposit Plate in Exit Stack, because Exit Stack is full or cannot hold Plate. Remove all Plates from Exit Stack and Manipulation Position. Press OK after removal of all Plates, else press Ignore.
TRP330_1	Could not transport Exit Lift to target position, Manipulation Position still occupied by Plate. Remove Plate from Manipulation Position. Press OK after removal of Plate from Manipulation Position.
TRP500_1	Exit Stack almost full. Next Plate deposit step might fail. Remove all Plates from Exit Stack.
TRP502_1	Exit Stack full. Can not deposit more Plates in Exit Stack. Remove all Plates from Exit Stack. Pressing Ignore will abort function!

DIALOG ID	MESSAGE
TRP900_1	Exit Lift not functioning. Move the Exit Lift manually into upper position. Press OK if manual intervention was successful, else press Ignore.
TRP901_1	Main Shuttle not functioning. Move the Main Shuttle manually into a collision-free position, outside of the Entry Lift or Exit Lift. Press OK if manual intervention was successful, else press Ignore.
TRP902_1	Main Shuttle not functioning. Move the Main Shuttle manually into a collision-free position, outside of the Entry Lift or Exit Lift. Press OK if manual intervention was successful, else press Ignore.
TRP903_1	Exit Lift not functioning. Move the Exit Lift manually into upper position. Press OK if your manual intervention was successful, else press Ignore.
COS810_1	The cover of the instrument has been opened. Only the main transport has stopped. Other functions of the instrument are still running. Danger of moving parts and contamination! Do not change the position of plates on the instrument! Close the cover as soon as possible to ensure proper processing of a running work list. Plates may be aborted if the cover is open too long.
COS811_1	The pause button of the instrument has been pressed. All functions of the instrument have stopped. Danger of contamination! Do not change the position of plates on the instrument! Press CONTINUE as soon as possible to ensure proper processing of a running work list. Plates may be aborted if the pause is activated too long.
DIA001_1	Cannot request instrument data. Check connection to instrument or call service representative.
DIA001_2	Firmware error. Start download procedure.
DIA002_1	Mismatch in technical data. Call service representative.
DIA003_1	Invalid instrument serial number. Call service representative.
DIA003_2	Different instrument connected. Press 'Continue' to use new instrument.
DIA003_3	Login with higher access rights.
DIA004_1	No or incompatible firmware loaded. Install and/or download new firmware.
DIA004_2	No or incompatible firmware loaded or no connection to External Bumptiousness. Call service representative.
DIA005_1	Instrument not adjusted. Call service representative.
DIA006_1	Different filters in instrument. Press 'Continue' to use filters in instrument.
DIA006_2	Login with higher access rights.
DIA007_1	Download for up-System '%s' aborted. Repair error and start download again.
INI001_1	Initialization of instrument failed due to fatal error Call a service representative
INI002_1	Heating up of incubators failed due to instrument failure Call a service representative

DIALOG ID	MESSAGE
ITP020_1	Module Transport of End Module is blocked or general Photometer error. Free Module Transport manually and clean Transport Plane and Photometer. Successful?.
ITP022_1	No plate detected on Module Transport of End Module. Check visually if a plate is present on the Module Transport of the End Module. Plate present?.
ITP032_1	Washer Lift is blocked or Wash Shell sensor has failed. Free the Washer Lift manually or clean and dry Wash Shell and sensor. Successful?
ITP033_1	Washer Lift is blocked or Wash Shell sensor is defect. Free the Washer Lift manually or Clean and/or dry Wash Shell and sensor. Successful?
ITP100_1	Incubator Module Transport will be unlocked. If there is a plate on the Module Transport remove it manually. Free Module Transport manually. Successful?
ITP101_1	Incubator Front Tower will be unlocked. If there is a plate on the Module Transport remove it manually. Free Module Transport and Front Tower manually. Successful?
ITP102_1	Incubator Rear Tower will be unlocked. If there is a plate on the Module Transport remove it manually. Free Module Transport and Rear Tower manually. Successful?
ITP110_1	Entry Lift will be unlocked. Free Entry Stack and Main Shuttle manually. Successful?
ITP120_1	Incubator Barcode Reader will be unlocked. If there is a plate on the Module Transport remove it manually. Clean MTP Barcode Reader manually. Successful?
ITP130_1	Washer Lift will be unlocked. If there is a plate on the Module Transport remove it manually. Free Module Transport and Washer Lift manually. Successful?
ITP140_1	Dispenser will be unlocked. Free Dispenser manually. Successful?
ITP141_1	Dispenser Module Transport will be unlocked. If there is a plate on the Module Transport remove it manually. Free Module Transport manually. Successful?
ITP150_1	Photometer will be unlocked. If there is a plate on the Module Transport remove it manually. Clean Module Transport, Transport Plane and Photometer manually. Successful?
ITP160_1	Main Shuttle will be unlocked. Remove all plates in collision area of the Main Shuttle manually. Free Main Shuttle manually. Successful?

DIALOG ID	MESSAGE
ITP161_1	Exit Lift will be unlocked. Remove any plates from the Exit Stack manually. Free Exit Stack manually. Successful?
ITP531_1	Barcode file not accessible due to corrupted Regneu.inf. Test cannot be processed! Call a service representative.
ITP532_1	Barcode file '%s' not found. Test cannot be processed! Call a service representative.
ITP533_1	Directory or File '%s' is locked. Test cannot be processed! Call a service representative.
ITP534_1	Corrupted barcode file '%s'. Test cannot be processed! Call a service representative.
ITP900_1	Unlocking of '%s' not successful. Call a service representative.
PTM900_1	Remove plate from manipulation position!
PTM910_1	Plate cannot be removed automatically. Open cover, remove plate at position '%s' by hand and close cover again! Have you removed the plate from instrument?
TPL001_1	The following test cannot be deleted because it is still located in the instrument Reinitialize the instrument and delete the test again

A1.1.3 Dispenser Errors

DIALOG ID	MESSAGE
DIS101_1	Could not initialize dispenser z-drive. Check for any obstruction in dispenser z-drive movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS103_1	Could not initialize module transport. Check for any obstruction in module transport movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS105_1	Could not initialize dispensing drive. Check for any obstruction in dispensing drive movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS106_1	Could not initialize dispenser rotor drive. Check for any obstruction in rotor movement and close reagent drawer. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS107_1	Could not initialize dispenser x-drive. Check for any obstruction in dispenser x-drive movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS301_1	Module transport step lost. Check for any obstruction in module transport movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS302_1	Module transport step lost. Check for any obstruction in module transport movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS312_1	Reagent rotor drive step lost. Check for any obstruction in rotor movement. Close drawer if manual intervention was successful, otherwise press IGNORE.
DIS322_1	Reagent rotor drive step lost. Check for any obstruction in rotor movement. Do not change the position of any container and close drawer if manual intervention was successful, otherwise press IGNORE.
DIS360_1	Syringe pickup failed. Dispensing drive step lost. Check syringe in container <%s> at position %d and change syringe if defective. Do not change the position of any container. Close drawer if manual intervention was successful, otherwise press IGNORE.
DIS361_1	Syringe pickup failed. Dispenser rotor drive step lost. Check syringe in container <%s> at position %d and change syringe if defective. Do not change the position of any container. Close drawer if manual intervention was successful, otherwise press IGNORE.
DIS362_1	Syringe pickup failed. Dispenser z-drive step lost. Check syringe in container <%s> at position %d and change syringe if defective. Do not change the position of any container. Close drawer if manual intervention was successful, otherwise press IGNORE.
DIS 363_1	Syringe pickup failed. No syringe grabbed. Check syringe in container <%s> at position %d and change syringe if defective. Do not change the position of any container. Close drawer if manual intervention was successful, otherwise press IGNORE.
DIS364_1	Dispenser x-drive step lost. Check for any obstruction in dispenser x-drive movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS373_1	Aspiration failed due to defective syringe. Replace syringe in container <%s> at position %d before next dispense.
DIS377_1	Aspiration failed due to defective syringe, foam or insufficient reagent in container. Check syringe for an air gap or foam. If completely filled with reagent press YES to start dispensing, otherwise press NO to abort plate. Do not change the position of any container.

DIALOG ID	MESSAGE
DIS377_2	Defective syringe or insufficient reagent in container. Replace syringe or check reagent in container <%s> at position %d before next dispense.
DIS384_1	Reagent rotor drive step lost. Check for any obstruction in rotor movement. Do not change the position of any container and close drawer if manual intervention was successful, otherwise press IGNORE.
DIS390_1	Dispenser x-drive step lost. Check for any obstruction in dispenser x-drive movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS391_1	Dispenser z-drive step lost. Check for any obstruction in dispenser z-drive movement. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS400_1	Dispenser x-drive step lost. Move dispenser x-drive manually to the drop position. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS402_1	Dispenser x-drive step lost. Move dispenser x-drive manually to the drop position. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS420_1	Operation interrupted due to an open reagent drawer. Do not change the position of the container with barcode <%s> at position %d and close reagent drawer immediately.
DIS421_1	Initialization interrupted due to an open reagent drawer. Close reagent drawer immediately.
DIS422_1	Operation interrupted due to an open reagent drawer. Close the reagent drawer immediately.
DIS501_1	Operation can not proceed due to an open reagent drawer. Close the reagent drawer immediately.
DIS502_1	Reagent containers inaccessible. Check the container(s) at position %s for parked syringe and that the cap is in service position. Close reagent drawer after checking.
DIS504_1	Syringe cannot be parked. Check the container at position %d for no parked syringe and that the cap is in service position. Close reagent drawer after checking.
DIS505_1	Containers at positions %s have the same barcode. Remove all duplicate containers and close reagent drawer.
DIS506_1	Service containers inaccessible. Check the service container(s) at position %s for no parked syringe and that the cap is in service position. Close reagent drawer after checking.
DIS507_1	No access to an empty service container for syringe check. Place an empty service container without syringe and close reagent drawer. Initialization will continue.
DIS508_1	Container of the used syringe is removed. Place the container with the barcode <%s> and close reagent drawer.
DIS512_1	Container at position %d with barcode <%s> is overfilled. Comply with reagent levels in the action list during next loading.
DIS521_1	No access to an empty service container for parking syringe. Place an empty service container without syringe and close reagent drawer. Initialization will continue.
DIS522_1	Syringe parked during initialization in container with barcode <%s> at position %d. To prevent contamination remove container.

DIALOG ID	MESSAGE
DIS523_1	Operation can not proceed due to an open reagent drawer. Close the reagent drawer immediately.
DIS541_1	Dispense failed due to defective syringe or foam in reagent container. Replace syringe in container with barcode <%s> at position %d before next aspiration.
DIS800_1	Power interruption detected. Please inform your instrument supplier and include the system trace. Program will continue.
DIS801_1	Power failure in ventilation system. Please inform your instrument supplier and include the system trace. Program will continue.
DIS805_1	Reagent drawer locked due to an operation in dispenser. Please wait until operation is finished.
DIS902_1	Module transport failure. Move the module transport manually into the module. Press OK if manual intervention was successful, otherwise press IGNORE.
DIS905_1	Syringe stuck in dispenser head. Danger: Do not try to remove syringe.

A1.1.4 Incubator Errors

DIALOG ID	MESSAGE
INC100_1	Couldn't pre-initialize the Front Tower Lift. Move the Front Tower manually into a collision-free position. Press OK after successful manual intervention.
INC100_2	Could not pre-initialize the Front Tower Lift. Move the Module Transport manually to the Main Shuttle and lower the Front Tower to the bottom position. Press OK if your intervention was successful, else press Ignore.
INC110_1	Couldn't pre-initialize or initialize the Rear Tower Lift. Move the Rear Tower manually into a collision-free position. Press OK after successful manual intervention.
INC120_1	Couldn't pre-initialize or initialize the Module Transport. Move the Module Transport manually into a collision-free position. Press OK after successful manual intervention.
INC120_2	Couldn't pre-initialize or initialize the Module Transport. Move the Module Transport manually into a collision-free position. Press OK if your manual intervention was successful, else press Ignore.
INC130_1	Could not pre-initialize or initialize the Entry Lift. Move the Entry Lift manually into a collision-free position. Press OK after successful manual intervention.
INC130_2	Could not pre-initialize or initialize the Entry Lift. Move the Entry Lift manually into the upper position. Press OK if your manual intervention was successful, else press Ignore.
INC140_1	Could not initialize the Front Tower Lift. Move the Front Tower manually into a collision-free position. Press OK after successful manual intervention.
INC140_2	Could not initialize the Front Tower Lift. Move the Front Tower manually into the lowest position. Press OK if your manual intervention was successful, else press Ignore.
INC160_1	Could not initialize the Plate Detection Sensor of the Entry Lift. Check whether space between Plate Sensors of the Entry Lift is blocked. Press OK after successful manual intervention.
INC170_1	Could not initialize the Plate Detection Sensor of the Module Transport. Check whether space between Plate Sensors of the Module Transport is blocked. Press OK after successful manual intervention.
INC360_1	Module Transport step lost. Could not execute Plate presence check in Incubator Slot. Move the Module Transport manually into a collision-free position. Press OK after successful manual intervention.
INC361_1	Front Tower Lift step lost. Could not execute Plate presence check in Incubator Slot. Move the Front Tower manually into a collision-free position. Press OK after successful manual intervention.
INC362_1	Rear Tower Lift step lost. Could not execute Plate presence check in Incubator Slot. Move the Rear Tower manually into a collision-free position. Press OK after successful manual intervention.
INC370_1	Module Transport step lost. Could not deposit Plate in Incubator Slot. Move the Module Transport manually into a collision-free position. Press OK after successful manual intervention.

DIALOG ID	MESSAGE
INC371_1	Front Tower Lift step lost. Could not deposit Plate in Incubator Slot. Move the Front Tower manually into a collision-free position. Press OK after successful manual intervention.
INC372_1	Rear Tower Lift step lost. Could not deposit Plate in Incubator Slot. Move the Rear Tower manually into a collision-free position. Press OK after successful manual intervention.
INC373_1 (FRONT)	Could not deposit Plate in the Incubator Slot %d of the Front Tower. Is there still a Plate on the Module Transport? Press Yes if a Plate is still present, else press No.
INC373_1 (REAR)	Could not deposit Plate in the Incubator Slot %d of the Rear Tower. Is there still a Plate on the Module Transport? Press Yes if a Plate is still present, else press No.
INC380_1	Module Transport step lost. Could not get plate from Incubator Slot. Move the Module Transport manually into a collision-free position. Press OK after successful manual intervention.
INC381_1	Front Tower Lift step lost. Could not get Plate from Incubator Slot. Move the Front Tower manually into a collision-free position. Press OK after successful manual intervention.
INC382_1	Rear Tower Lift step lost. Could not get Plate from Incubator Slot. Move the Rear Tower manually into a collision-free position. Press OK after successful manual intervention.
INC383_1 (FRONT)	Could not get Plate from the Incubator Slot %d of the Front Tower. Is there still a Plate in the Incubator Slot %d of the Front Tower? Press Yes if a Plate is still present, else press No.
INC383_1 (REAR)	Could not get Plate from the Incubator Slot %d of the Rear Tower. Is there still a Plate in the Incubator Slot %d of the Front Tower? Press Yes if a Plate is still present, else press No.
INC403_1	Module Transport step lost. Could not read Plate Barcode. Check the Plate on the Module Transport for correct positioning. Press OK if the Plate is in correct position.
INC407_1	Main Shuttle step lost. Could not read Plate Barcode. Check the Plate on the Main Shuttle for correct positioning. Press OK if the Plate is in correct position.
INC420_1	Entry Lift movement interrupted by user. Continue movement of the Entry Lift? Press YES to continue. NO will abort the loading.
INC421_1	Entry Lift step lost. Could not execute Plate presence check on the Entry Stack. Check the Plates on the Entry Stack for correct positioning. Press OK if the Plates are in correct position.
INC422_1	Stack has not been loaded. To continue Plate loading press YES. NO will abort this function.
INC425_1	Entry Lift movement interrupted by user. Continue movement of the Entry Lift? Press YES to continue. NO will abort the loading.
INC510_1	State of Entry Stack is reserved. Do not press Load Button while LED is yellow blinking.
INC800_1	Power interruption detected. Please inform your instrument supplier and include the system trace. Program will continue.
INC801_1	Power failure in ventilation system. Please inform your instrument supplier and include the system trace. Program will continue.

DIALOG ID	MESSAGE
INC900_1	Module Transport not functioning. Move the Module Transport manually into a collision-free position. Press OK if manual intervention was successful, else press Ignore.
INC901_1	Front Tower Lift not functioning. Move the Front Tower manually into the lowest position. Press OK if manual intervention was successful, else press Ignore.
INC903_1	Entry Lift not functioning. Move the Entry Lift manually into the upper position. Press OK, if manual intervention was successful, else press Ignore.

A1.1.5 Washer Errors

DIALOG ID	MESSAGE
WAS332_1	Water Separator overflow. Check whether Waste Tubing and Waste Container are connected and correct manually, if necessary. Press OK if your manual intervention was successful, else press Ignore.
WAS333_1	Water Separator overflow. Check whether Waste Tubing and Waste Container are connected and correct manually, if necessary. Press OK if your manual intervention was successful, else press Ignore.
WAS340_1	DO NOT OPEN Fluid Connector while rinse procedure running. Connect Fluid Container %d to wash (horizontal) position and Fluid Connector %d to rinse (vertical) position. Pressing Ignore will abort function!
WAS344_1	Dispense Pump OVERLOAD during rinse procedure. Check Wash Fluid Tubing for bends or kinks and correct if necessary. Press OK if your manual intervention was successful, else press Ignore.
WAS346_1	Vacuum Pump OVERLOAD. Check Waste Tubing for bends or kinks and adjust if necessary. Press OK if your manual intervention was successful, else press Ignore.
WAS349_1	Vacuum Pump OVERLOAD. Check Waste Tubing for bends or kinks and adjust if necessary. Check Sterile Filter. Press OK if your manual intervention was successful, else press Ignore.
WAS360_1	Water Separator overflow during wash procedure. Check Waste Tubing or Waste Container disconnected and correct if necessary. Press OK if your manual intervention was successful, else press Ignore.
WAS366_1	DO NOT OPEN Fluid Connector while wash procedure running. Connect Fluid Container %d to wash (horizontal) position immediately. Press OK if Fluid Connector already on wash position. Pressing Ignore will abort wash function
WAS368_1	Dispense Pump OVERLOAD during wash procedure. Check Wash Fluid Tubing for bends or kinks and adjust if necessary. Press OK if your manual intervention was successful, else press Ignore.
WAS370_1	Vacuum Pump OVERLOAD during wash procedure. Check Waste Tubing for bends of kinks and adjust if necessary. Press OK if your manual intervention was successful, else press Ignore.
WAS372_1	No communication 'RS232' to external pump station Check cable to external Pump Station for connection. Press OK if your manual intervention was successful, else press Ignore.

DIALOG ID	MESSAGE
WAS380_1	Plate wash operation not successful due to improper aspiration or dispensing of wash fluid. Check Wash Fluid and Waste Fluid Tubing for bends or kinks and adjust if necessary. Press OK to continue.
WAS450_1	No communication 'RS232' to external Pump Station Check cable to external Pump Station for connection. Press OK if your manual intervention was successful, else press Ignore.
WAS500_1	Waste Cap must be on Waste Container. Place Waste Cap on Waste Container. Pressing Ignore will abort function!
WAS510_1	Waste Container full. Empty Waste Container immediately. Pressing Ignore will abort function!
WAS530_1	Waste Container full while function running. Empty Waste Container first, function will continue with disconnected waste cap. Pressing Ignore will abort function!
WAS542_1	Insufficient liquid in Fluid Container %d. Refill Fluid Container %d immediately. Pressing Ignore will abort function!
WAS552_1	Fluid Connector of Container %d not in rinse (vertical) position. Connect Fluid Container %d to rinse (vertical) position. Pressing Ignore will abort function!
WAS554_1	Container with Rinse fluid not on position %d. Load Container with Rinse fluid on position %d. Press OK when Rinse fluid loaded. Pressing Ignore will abort function!
WAS560_1	Waste Container almost full. Empty Waste Container.
WAS562_1	Waste Container full. Do not put the Waste Cap on a full Waste Container. Empty Waste Container first.
WAS564_1	Fluid '%s' in Container %d almost empty. Refill before next operation on Washer.
WAS566_1	Wash Channel %d locked. Load Container on different Channel. Pressing Ignore will abort function!

A1.2 Trace Messages

The following tables list the messages that can appear in traces.

A1.2.1 Explanation of Trace Codes

Trace messages are grouped together in even and odd pairs. For instance, the following two entries are associated with the same trace message:

32000 NOTE RUN Washing started (wash solution '%s'; barcode '%s'; comp.lot.nr-1 '%s'; comp.lot.nr-2 '%s'; volume '%u µl'; soak time '%u sec'); location '%s'
32001 loc=%s;fluid=%s;bc=%s;lot1=%s;lot2=%s;vol=%d;sec=%d;

The first entry is the complete trace message. The second entry gives only the parameters (if any) that vary in the trace message, e.g. module, wash volume, soak time, etc. These parameters are intended for evaluation by external applications.

The special character '%', followed by a format character (e.g. 's' for string, 'd' for decimal, etc.), is used in the trace messages as a placeholder for dynamic entries and will be replaced by different text in the actual trace messages:

For example, the message:

32016 NOTE RUN Dispensing started (reagent '%s'; barcode '%s'; comp.lot.nr-1 '%s'; comp.lot.nr-2 '%s'; volume per well '%u µl'); location '%s'
32017 loc=%s;fluid=%s;bc=%s;lot1=%s;lot2=%s; vol=%d;

might appear on the screen as:

32016 NOTE RUN Dispensing started (reagent 'Stop Solution'; barcode 'REAGENT 13.00'; comp.lot.nr-1 'KL-1'; comp.lot.nr-2 'KL-2'; volume per well '100 µl'); location 'Dispenser 1'
32017 loc=D1;fluid=Stop Soluion;bc=REAGENT 13.00;lot1=KL-1;lot2=KL-2;vol=100;

A1.2.2 Test-Trace Messages

Trace ID	Message
10000	NOTE RUN µP-System '%s'; firmware version '%s'
10002	NOTE RUN Instrument serial number '%s'
10004	NOTE RUN µP-System '%s'; serial number '%s'
11592	WARNING VRY Photometer verification required; location '%s'; Error Status = Trace
11593	loc=P0;
11594	WARNING VRY Dispenser verification required; location '%s'; Error Status = Trace
11595	loc=D%d;
11596	WARNING VRY Washer verification required; location '%s'; Error Status = Trace
11597	loc=W%d;

11598	WARNING VRY Incubator slot verification required; location '%s'; Error Status = Trace
11599	loc=%s;tow=f;slot=%c;slot=%c;slot=%c;slot=%c;slot=%c; tow=r;slot=%c;slot=%c;slot=%c;slot=%c;slot=%c;
14460	NOTE USER Test documentation started manually (user '%s')
14466	NOTE DOCU The file link command '%s' to external '%s' was executed successfully. Waiting for confirmation from fam_rtc
14468	ERROR DOCU The file link command '%s' to external '%s' was confirmed by fam_rtc as NOT successful
14470	ERROR DOCU The file link command '%s' to external '%s' was NOT confirmed by fam_rtc before timeout was reached
14472	NOTE DOCU Documentation jobs finished successfullyRun Status = Documented
14476	NOTE DOCU The file link command '%s' to external '%s' was confirmed by fam_rtc as successful
14478	ERROR DOCU A system error occurred during documentation of the test
14480	NOTE DOCU The test was documented on the '%s' printer
14482	ERROR DOCU The documentation job on the '%s' printer was not successful
14484	WARNING USER Operator excluded one or more wells or inserted one or more well comments. Error Status = Trace
14488	NOTE USER <Test trace comment entered by the user>
14500	ERROR CTRL 'WAS320', Manifold missing (error code '%d'); location '%s'
14502	ERROR CTRL 'WAS360', Water Separator overflow during procedure running (error code '%d'); location '%s'
14504	ERROR CTRL 'WAS366', Fluid Connector opened during procedure running (error code '%d'); location '%s'
14506	ERROR CTRL 'WAS368', overload Dispensing Pump during procedure running (error code '%d'); location '%s'
14508	ERROR CTRL 'WAS370', overload Vacuum Pump during procedure running (error code '%d'); location '%s'
14510	ERROR CTRL 'WAS372', no communication to external Pump Station (error code '%d'); location '%s'
14512	ERROR CTRL 'WAS380', improper Wash Fluid aspirating or dispensing (error code '%d'); location '%s'
14514	ERROR CTRL 'WAS382', blocked Aspirating or Dispensing Needle (error code '%d'); location '%s'
14516	ERROR CTRL 'WAS383', blocked Dispensing Needle (error code '%d'); location '%s'
14518	ERROR CTRL 'WAS384', Z-Movement Manifold step lost (error code '%d'); location '%s'
14520	ERROR CTRL 'WAS386', Module Transport of Dispenser step lost (error code '%d'); location '%s'
14522	ERROR CTRL 'WAS390', Waste or Vacuum Pump not connected (error code '%d'); location '%s'
14524	ERROR CTRL 'WAS400', Manifold not calibrated (error code '%d'); location '%s'
14526	ERROR CTRL 'WAS500', waste cap not on waste container (error code '%d'); location '%s'
14528	ERROR CTRL 'WAS510', waste container full (error code '%d'); location '%s'
14530	ERROR CTRL 'WAS530', waste container full (error code '%d'); location '%s'
14532	ERROR CTRL 'WAS540', missing fluid container (error code '%d'); location '%s'
14534	ERROR CTRL 'WAS542', missing level in fluid container (error code '%d'); location '%s'
14536	ERROR CTRL 'WAS406', Module Transport from Dispenser not initialized (error code '%d'); location '%s'

14538	ERROR CTRL 'WAS408', syntax error from Dispenser (error code '%d'); location '%s'
14540	ERROR CTRL 'WAS410', communication error to Dispenser (error code '%d'); location '%s'
14542	ERROR CTRL 'WAS412', no parallel function with Module Transport of Dispenser (error code '%d'); location '%s'
16602	NOTE TEST Recovery detected plate; location '%s'
16604	NOTE TEST Plate moved to '%s'
16606	NOTE TEST Test created (Test-id='%d')
16608	NOTE USER Plate removed manually from instrument
16610	NOTE TEST Run state set to '%s'
16612	NOTE TEST Error state set to '%s'
16614	NOTE TEST Well data have been written
16616	NOTE TEST Photo data have been written
16618	NOTE TEST Sram data have been written
16620	ERROR START Instrument startup while test running Run Status = Processed Error Status = Aborted
16624	WARNING TEST Plate position not set: Position is occupied by test '%d'; location '%s'
16632	NOTE TEST Methode: '%s', Created: '%s %s', M-Code: '%ld'
16634	NOTE TEST Usersoftware version '%s'
16636	NOTE TEST DB version '%s'
16638	NOTE TEST Currently logged in user '%s'
16640	NOTE TEST New user logged in '%s'
17000	ERROR CTRL 'TRP300', Main Shuttle step lost, (error code '%d'); location '%s'
17002	ERROR CTRL 'TRP301', Main Shuttle wrong position parameter detected (%s), (error code '%d'); location '%s'
17004	ERROR CTRL 'TRP310', Exit Lift step lost, (error code '%d'); location '%s'
17006	ERROR CTRL 'TRP320', bad stacking of Plate, (error code '%d'); location '%s'
17008	ERROR CTRL 'TRP330', still holding Plate on Manipulation Position, could not stack Plate, (error code '%d'); location '%s'
17010	ERROR CTRL 'TRP330', still holding Plate on Manipulation Position again, (error code '%d'); location '%s'
17500	NOTE MAINT Cold Start maintenance status '%s'
17501	maint=%c;
17502	NOTE MAINT Daily maintenance status '%s'
17503	maint=%c;
17504	NOTE MAINT Weekly maintenance status '%s'
17505	maint=%c;
17506	NOTE MAINT Monthly maintenance status '%s'
17507	maint=%c;
19500	ERROR CTRL INC300, Module Transport step lost (error code '%d'); location '%s'
19502	ERROR CTRL INC310, Front Tower Lift step lost (error code '%d'); location '%s'
19504	ERROR CTRL INC330, Entry Lift step lost (error code '%d'); location '%s'
19506	ERROR CTRL INC350, Module Transport step lost (error code '%d'); location '%s'
19508	ERROR CTRL INC351, Front Tower Lift step lost (error code '%d'); location '%s'
19510	ERROR CTRL INC370, Module Transport step lost (error code '%d'); location '%s'
19512	ERROR CTRL INC371, Front Tower Lift step lost (error code '%d'); location '%s'
19514	ERROR CTRL INC372, Rear Tower Lift step lost (error code '%d'); location '%s'

19516	ERROR CTRL INC373, could not deposit Plate in Incubator Slot (error code '%d'); location '%s'
19518	ERROR CTRL INC380, Module Transport step lost (error code '%d'); location '%s'
19520	ERROR CTRL INC381, Front Tower Lift step lost (error code '%d'); location '%s'
19522	ERROR CTRL INC382, Rear Tower Lift step lost (error code '%d'); location '%s'
19524	ERROR CTRL INC383, could not get Plate from Incubator Slot (error code '%d'); location '%s'
19526	ERROR CTRL INC400, Plate Barcode Reader hardware error (error code '%d'); location '%s'
19528	ERROR CTRL INC402, Plate Barcode not readable (error code '%d'); location '%s'
19530	ERROR CTRL INC403, Module Transport step lost (error code '%d'); location '%s'
19532	ERROR CTRL INC404, Front Tower Lift step lost (error code '%d'); location '%s'
19534	ERROR CTRL INC405, Communication error in Exit System (error code '%d'); location '%s'
19536	ERROR CTRL INC407, Main Shuttle step lost (error code '%d'); location '%s'
20000	NOTE RUN Test processing finished. Run Status = Processed
20002	ERROR RUN Test aborted due to processing error. Run Status = Processed Error Status = Aborted
20004	ERROR RUN Test aborted by user. Run Status = Processed Error Status = Aborted
20006	ERROR RUN Test aborted due to run abort by user. Run Status = Processed Error Status = Aborted
20008	ERROR RUN Test aborted due to run abort by system. Run Status = Processed Error Status = Aborted
20010	ERROR RUN Test aborted due to schedule limitations. Run Status = Processed Error Status = Aborted
20012	ERROR RUN Test aborted due to plate not loaded by user. Run Status = Processed Error Status = Aborted
21500	ERROR CTRL 'DIS301', module transport step lost (error code '%d'); location '%s'
21502	ERROR CTRL 'DIS302', module transport step lost (error code '%d'); location '%s'
21504	ERROR CTRL 'DIS303', shaking time was reduced by %ld seconds; location '%s' Error Status = Error
21505	loc=%s;sec=%ld;err=%d;
21506	ERROR CTRL 'DIS303', module transport step lost (error code '%d'); location '%s'
21508	ERROR CTRL 'DIS371', dispenser z-drive step lost (error code '%d'); location '%s'
21510	ERROR CTRL 'DIS373', dispensing drive step lost (error code '%d'); location '%s'
21512	ERROR CTRL 'DIS377', aspiration approved as valid by the operator; location '%s' Error Status = Error
21513	loc=%s;err=%d;

21514	ERROR CTRL 'DIS377', improper aspiration (error code '%d'); location '%s' Error Status = Error
21516	ERROR CTRL 'DIS378', liquid level detection defective (error code '%d'); location '%s'
21518	ERROR CTRL 'DIS382', liquid level detection defective (error code '%d'); location '%s'
21520	ERROR CTRL 'DIS383', no liquid detected (error code '%d'); location '%s'
21522	ERROR CTRL 'DIS384', dispenser rotor drive step lost (error code '%d'); location '%s'
21524	ERROR CTRL 'DIS390', dispenser x-drive step lost (error code '%d'); location '%s'
21526	ERROR CTRL 'DIS391', dispenser z-drive step lost (error code '%d'); location '%s'
21530	ERROR CTRL 'DIS400', dispenser x-drive step lost, well flags changed (error code '%d'); location '%s' Error Status = Trace
21534	ERROR CTRL 'DIS401', module transport step lost, well flags changed (error code '%d'); location '%s' Error Status = Trace
21538	ERROR CTRL 'DIS402', dispensing drive step lost, well flags changed; location '%s' Error Status = Trace
21539	loc=%s;err=%d;
21542	ERROR CTRL 'DIS402', dispensing drive step lost, well flags changed (error code '%d'); location '%s' Error Status = Trace
21544	ERROR CTRL 'DIS411', dispenser z-drive step lost (error code '%d'); location '%s' Error Status = Error
21546	ERROR CTRL 'DIS412', dispenser rotor drive step lost (error code '%d'); location '%s' Error Status = Error
21548	ERROR CTRL 'DIS413', dispensing drive step lost (error code '%d'); location '%s' Error Status = Error
21549	loc=%s;err=%d;
21550	ERROR CTRL 'DIS414', dispenser x-drive step lost (error code '%d'); location '%s' Error Status = Error
21552	ERROR CTRL 'DIS511', not enough reagent (container volume '%ld ul'; error code '%d'); location '%s'
21554	ERROR CTRL 'DIS513', reagent container missing (error code '%d'); location '%s'
21556	ERROR CTRL 'DIS514', could not start aspiration step, step timeout (error code '%d'); location '%s'
21558	ERROR CTRL 'DIS541', improper dispensation (error code '%d'); location '%s' Error Status = Error
21559	loc=%s;err=%d
21560	ERROR CTRL 'DIS551', could not start step, dispenser has been locked (error code '%d'); location '%s'
21562	ERROR CTRL 'DIS900', dispenser has been locked (error code '%d'); location '%s'
21564	ERROR CTRL 'DIS901', dispenser has been locked (error code '%d'); location '%s'
21566	ERROR CTRL 'DIS902', module transport has been locked (error code '%d'); location '%s'
21568	ERROR CTRL 'DIS905', dispenser has been locked (error code '%d'); location '%s'

21570	ERROR CTRL 'DIS306', dispensing drive step lost (error code '%d'); location '%s'
24510	WARNING CTRL PTM112 occurred, plate transport aborted (error code '%d')
24520	WARNING CTRL PTM500 occurred, plate transport aborted (reason '%s')
24522	WARNING CTRL PTM500 occurred, plate transport not aborted (reason '%s')
31500	ERROR CTRL 'FOT003', command failed while not initialized (error code '%d'); location '%s'
31502	ERROR CTRL 'FOT300', error in reply string of measurement data (error code '%d'); location '%s'
31504	ERROR CTRL 'FOT302', error in reply string of measurement data (error code '%d'); location '%s'
31506	ERROR CTRL 'FOT311', measurement request command failed (error code '%d'); location '%s'
32000	NOTE RUN Washing started (wash solution '%s'; barcode '%s'; comp.lot.nr-1 '%s'; comp.lot.nr-2 '%s'; volume '%u µl'; soak time '%u sec'); location '%s'
32001	loc=%s;fluid=%s;bc=%s;lot1=%s;lot2=%s;vol=%d;sec=%d;
32002	ERROR RUN Washing start failed (reason '%s'); location '%s' Error Status = Error
32003	loc=%s;
32004	NOTE RUN Washing finished successfully; location '%s'
32005	loc=%s;
32006	ERROR RUN Washing finished with error; location '%s' Error Status = Error
32007	loc=%s;
32008	NOTE RUN Aspirating started; location '%s'
32009	loc=%s;
32010	ERROR RUN Aspirating start failed (reason '%s'); location '%s' Error Status = Error
32011	loc=%s;
32012	NOTE RUN Aspirating finished successfully (reagent '%s'; barcode '%s'; comp.lot.nr-1 '%s'; comp.lot.nr-2 '%s'; volume '%u µl'); location '%s'
32013	loc=%s;fluid=%s;bc=%s;lot1=%s;lot2=%s;vol=%d;
32014	ERROR RUN Aspirating finished with error; location '%s' Error Status = Error
32015	loc=%s;
32016	NOTE RUN Dispensing started (reagent '%s'; barcode '%s'; comp.lot.nr-1 '%s'; comp.lot.nr-2 '%s'; volume per well '%u µl'); location '%s'
32017	loc=%s;fluid=%s;bc=%s;lot1=%s;lot2=%s;vol=%d;
32018	ERROR RUN Dispensing start failed (reason '%s'); location '%s' Error Status = Error
32019	loc=%s;
32020	NOTE RUN Dispensing finished successfully; location '%s'
32021	loc=%s;
32022	ERROR RUN Dispensing finished with error; location '%s' Error Status = Error
32023	loc=%s;
32024	NOTE RUN Mixing started (intensity '%s'; duration '%u sec'); location '%s'
32025	loc=%s;int=%c;sec=%d;
32026	ERROR RUN Mixing start failed (reason '%s'); location '%s' Error Status = Error
32027	loc=%s;
32028	NOTE RUN Mixing finished successfully; location '%s'
32029	loc=%s;
32030	ERROR RUN Mixing finished with error; location '%s' Error Status = Error
32031	loc=%s;

32032	NOTE RUN Photometer reading started (mode '%s'; filter '%d nm'; ref. filter '%d nm')
32033	phot=%c;meas=%d;ref=%d;
32036	NOTE RUN Photometer reading finished successfully
32038	ERROR RUN Photometer reading finished with error Error Status = Error
32040	NOTE RUN SRAM passed (blank corr. '%s'; abs.limits '%+4.3f/%+4.3f'; median '%s'; dev.limits '%s/%s')
32041	bcorr=%s;abslim=%+4.3f/%+4.3f;median=%s;devlim=%s/%s;
32042	WARNING RUN SRAM passed with warnings (blank corr. '%s'; abs.limits '%+4.3f/%+4.3f'; median '%s'; dev.limits '%s/%s') Error Status = Trace
32043	bcorr=%s;abslim=%+4.3f/%+4.3f;median=%s;devlim=%s/%s;
32044	WARNING RUN SRAM failed for one or more wells (blank corr. '%s'; abs.limits '%+4.3f/%+4.3f'; median '%s'; dev.limits '%s/%s') Error Status = Trace
32045	bcorr=%s;abslim=%+4.3f/%+4.3f;median=%s;devlim=%s/%s;
32046	ERROR RUN SRAM failed (reason 'no valid blank available') Error Status = Trace
32048	WARNING RUN Blank correction evaluated with only %d valid blank(s) out of %d Error Status = Trace
32062	NOTE RUN Priming started; location '%s'
32063	loc=%s;
32064	ERROR RUN Priming start failed (reason '%s'); location '%s' Error Status = Error
32065	loc=%s;
32066	NOTE RUN Priming finished successfully (wash solution '%s'; barcode '%s'; comp.lot.nr-1 '%s'; comp.lot.nr-2 '%s'); location '%s'
32067	loc=%s;fluid=%s;bc=%s;lot1=%s;lot2=%s;
32068	ERROR RUN Priming finished with error; location '%s'S Error Status = Error
32069	loc=%s;
32070	NOTE RUN Incubation started (time '%s'; slot temperature '%s °C'); location '%s'
32071	loc=%s;tow=%c;slot=%d;time=%s;temp=%s;
32072	ERROR RUN Incubation start failed; location '%s' Error Status = Error
32073	loc=%s;tow=%c;slot=%d;
32074	NOTE RUN Incubation finished (time '%s'; slot temperature '%s °C'); location '%s'
32075	loc=%s;tow=%c;slot=%d;time=%s;temp=%s;
32076	ERROR RUN Incubation finished with error; location '%s' Error Status = Error
32077	loc=%s;tow=%c;slot=%d;
32078	ERROR RUN Test information from sampler: Run interrupted Error Status = Error
32080	WARNING RUN Pipetting errors reported from sampler Error Status = Trace
32082	NOTE RUN Barcode file read successfully (filename '%s')
32083	file=%s;
32084	NOTE RUN Plate barcode verified at reidentification (barcode read '%s')
32085	bc=%s;
32086	WARNING RUN Plate barcode not verified because barcode manually entered at loading
32088	NOTE RUN Plate accepted (barcode '%s', identification mode '%s')
32089	bc=%s;ident=%c;
32090	WARNING USER Operator included one or more wells Error Status = Trace
32092	WARNING USER Operator excluded one or more wells Error Status = Trace

32094	WARNING USER Operator changed one or more well barcodes Error Status = Trace
32096	WARNING RUN Different barcodes found for replicate wells or controls of same type. Error Status = Trace
32100	ERROR RUN ITP002: Step could not be executed Error Status = Error
32102	ERROR RUN ITP010: Syringe check failed; location '%s' Error Status = Error
32104	ERROR RUN ITP020: Module transport error during photometric measurement Error Status = Error
32106	ERROR RUN ITP021: Error in photometer or firmware during photometric measurement Error Status = Error
32108	ERROR RUN ITP024: Not all wells detected or general photometer failure. Error Status = Error
32110	ERROR RUN ITP022: Plate not detected during photometric measurement Error Status = Error
32112	ERROR RUN ITP023: Photometer locked due to dispenser module transport failure Error Status = Error
32114	ERROR RUN ITP032: Washer locked due to an error during priming; location '%s' Error Status = Error
32116	ERROR RUN ITP040: Plate transport failure (plate still on instrument); location '%s'
32118	ERROR RUN ITP040: Plate transport failure (plate no longer on instrument)
32120	ERROR RUN ITP500: Incubation time not within tolerance; location '%s' Error Status = Error
32121	loc=%s;tow=%c;slot=%d;
32122	ERROR RUN ITP500: End of incubation undefined; location '%s' Error Status = Error
32123	loc=%s;tow=%c;slot=%d;
32124	ERROR RUN ITP500: Start of incubation undefined; location '%s' Error Status = Error
32125	loc=%s;tow=%c;slot=%d;
32126	ERROR RUN ITP501: No incubator slot available Error Status = Error
32128	ERROR RUN ITP510: Plate no longer on instrument Error Status = Error
32130	ERROR RUN ITP511: Plate barcode could not be read during reidentification Error Status = Error
32132	ERROR RUN ITP512: Wrong plate detected during reidentify (barcode read '%s') Error Status = Error
32133	bc=%s;
32134	ERROR RUN ITP520: Plate hold time exceeded Error Status = Error
32136	ERROR RUN ITP530: Plate not loaded (load time exceeded) Error Status = Error
32138	ERROR RUN ITP800: Incubation temperature exceeded safety tolerance band or sensor defective; location '%s' Error Status = Error
32139	loc=%s;tow=%c;slot=%d;
32140	ERROR RUN ITP801: Incubation temperature exceeded limits defined in method; location '%s' Error Status = Error

32141	loc=%s;tow=%c;slot=%d;
32142	ERROR RUN ITP531: Barcode file not accessible due to corrupted Regneu.inf Error Status = Error
32144	ERROR RUN ITP532: Barcode file not found (filename '%s') Error Status = Error
32145	file=%s;
32146	ERROR RUN ITP533: Barcode directory is locked (directory '%s') Error Status = Error
32147	dir=%s;
32148	ERROR RUN ITP534: Barcode file corrupt (filename '%s') Error Status = Error
32149	file=%s;
32150	ERROR RUN ITP540: No plate at required position for washing or dispensing; location '%s' Error Status = Error
32151	loc=%s;
32152	ERROR RUN ITP541: Fluid stability time exceeded (fluid '%s'; barcode '%s'; comp.lot.nr-1 '%s'; comp.lot.nr-2 '%s') Error Status = Error
32153	loc=%s;fluid=%s;bc=%s;lot1=%s;lot2=%s;
32154	ERROR RUN ITP803: Step not started due to wrong instrument state (step '%s'); location '%s'
32156	ERROR RUN ITP535: Plate not loaded (aborted by user) Error Status = Error
32158	ERROR RUN ITP536: Plate loading finished (test abort requested by user) Error Status = Error
32160	NOTE RUN ITP537: Plate loading finished (edit plate requested by user)
32162	ERROR RUN ITP538: Plate loading finished with error Error Status = Error
32164	ERROR RUN ITP539: No pipetting information found Error Status = Error
32166	NOTE RUN Plate loading started (%s; %s; kit lot '%s')
32167	pa=%s;klt=%s;kitlot=%s;
32168	NOTE RUN Plate loading finished
32170	NOTE RUN Well identification started
32172	NOTE RUN Well identification finished (kit lot '%s'; time stamp '%s')
32173	kitlot=%s;time=%s;

A1.2.3 Well-Trace Messages

Trace ID	Message
14490	NOTE USER Well excluded manually (user '%s') Well flag = ex
14492	NOTE USER <Well trace comment entered by user> Well flag = tr
16702	NOTE TEST Well flag set to '%s'
16704	NOTE TEST Well barcode set to '%s'
21528	ERROR CTRL 'DIS400', well not dispensed; location '%s' Well flag = ex
21532	ERROR CTRL 'DIS401', well not dispensed; location '%s' Well flag = ex
21536	ERROR CTRL 'DIS402', well unusable; location '%s' Well flag = ex
21540	ERROR CTRL 'DIS402', well not dispensed; location '%s' Well flag = ex
32180	ERROR RUN ': Pipetting error from sampler (code '%d') Well Flag = tr
32182	WARNING RUN Pipetting warning from sampler (code '%d') Well Flag = tr
32184	ERROR RUN Plate layout error (barcode not identical with well '%s') Well Flag = tr
32186	WARNING USER Operator included well for processing Well Flag = tr
32188	WARNING USER Operator excluded well from processing Well Flag = ex
32190	WARNING USER Operator changed well barcode (previous '%s'; new '%s') Well Flag = tr
32192	ERROR RUN Invalid measurement OD (meas. '%s'; ref. '%s') Well Flag = tr
32194	ERROR RUN Invalid reference OD (meas. '%s'; ref. '%s') Well Flag = tr
32196	ERROR RUN Absolute OD limit exceeded (meas. '%s'; ref. '%s'; blank corr. '%s'; calc.OD '%+4.3f'; abs.limits '%+4.3f/%+4.3f') Well Flag = tr
32198	ERROR RUN Deviation from median exceeded (meas. '%s'; ref. '%s'; blank corr. '%s'; median '%s'; calc.OD '%+4.3f'; dev.limits '%s/%s') Well Flag = tr

Appendix 2 Glossary

Access Level	Right for using different functions of the user software, e.g. reading, editing, etc.
Access Right	The specific access right needed to carry out a certain function with the user software.
Action List	A list of instructions generated by the user software which gives all the steps that the user has to carry out during the execution of a work list (this information can only be printed, i.e. it can not be viewed from within the Work List Manager).
Archive	A long term store of test data. Will not be done by the user software.
Aspirating Needle	The needle which aspirates fluid from the well during the wash procedure. The longer needles in the washer manifold.
ASTM Format	Standardized file format used for host result reports (ASTM = American Society for Testing and Materials).
Barcode Mask	Definition of the basic format of a plate barcode. Can consist of fixed characters which appear on every barcode, and wildcards for test no., kit lot no. and other data.
Barcode Scanner	Hand held barcode scanner - See also : **MTP Barcode Reader**.
Base Time	A reference point used in a work list relative to which, stack loading times are defined.
CAg/Ag-Coating	Special type of assay using antigen and control antigen coated wells for each control and sample (for individual well blank correction).
Chassis	Component of ML F.A.M.E. instrument onto which modules are mounted, holding them in position.
Chassis Expansion	Allows the addition of a further module to each side of the chassis.
Check Plate	General term for an MTP-sized device used to test certain instrument functions.
Cold Start	An instrument initialisation procedure which is executed (by the user software) at start-up, after a shutdown has previously been executed, or at start-up, after a certain time has elapsed since the last connection to the instrument.
Competitive Test	A test in which a specific antibody being tested for in a sample is in competition with the same specific antibody (however conjugated with an enzyme) contained in a reagent.
Conjugate	Enzyme-linked antibody used in an assay.
Container Stack	Frame which holds up to two external pump stations.
Control	A sample like material used for evaluation and validation of qualitative and semi-quantitative assays.
Device	An external piece of equipment used together with the ML F.A.M.E..
Dispenser	Short form: Disp. Device which picks up a syringe and dispenses accurate volumes of liquid into an MTP.
Dispenser End Module	Short form: Dispenser/End or Disp./End. Part of the End Module that picks up a syringe and dispenses accurate volumes of liquid into an MTP.

Dispenser Washer/Disp. Module 1	Short form: Dispenser 1. Part of Washer/Disp. Module 1 that picks up a syringe and dispenses accurate volumes of liquid into an MTP.
Dispenser Washer/Disp. Module 2	Short form: Dispenser 2. Part of Washer/Disp. Module 2 that picks up a syringe and dispenses accurate volumes of liquid into an MTP.
Dispensing Needle	The needle that dispenses wash fluid into a well. The shorter needle in the washer manifold.
Display Priority	A precedence level that determines which priority of trace message is displayed/ printed.
Disposable Syringe	Syringe used by dispenser for pipetting reagent into wells.
Disposable Tip/Barrel	The outer part of the disposable syringe. Houses the disposable plunger.
Documentation Definition	Part of a method definition that defines a list of documentation jobs to be executed as part of the documentation process of a test. Whenever a test is released or redocumented it is documented according to this job list.
Documentation Format	Definition of what kind of data from a test has to be included in printouts or result files. User programmable parameters for the content of a result file or a print out.
Documentation Job	Part of the documentation definition that determines to where a test result report (in a given documentation format) is sent, e.g. host computer, printer, etc.
Document Test	The action of documenting a test as specified in the method definition.
Drop-down List	A field in a window or dialog box with a control icon, which when opened (by clicking on its control icon) displays a list of objects (items) from which one can be selected.
Editor	Part of the ML F.A.M.E. software used to manipulate data.
ELISA	Enzyme-Linked Immuno Sorbent Assay.
Entry Lift	Device which moves the entry stack up and down.
Entry Platform	Part of the entry lift upon which an entry stack or a single MTP may be placed.
Entry Section	The MTP entry area of the instrument.
Entry Stack	Device for loading MTPs into the instrument. Can hold up to 4 MTPs. Can also be used as MTP carrier for “in laboratory” use.
Error Status	Gives information on the validity of test results, i.e., None - no errors occurred, Trace - at least one well was flagged, Error - an error occurred during pipetting or during test processing (can not be determined exactly), Aborted - the test was aborted before the completion of all steps.
Exit Lift	Device which moves MTPs into the exit stack or to the manipulation position.
Exit Stack	Area of instrument from where finished plates may be removed. Holds up to 10 MTPs.
External Pump Station	Device that selects a wash fluid and pumps it to the manifold.
External Water Separator	Holds waste fluid which has been expelled from the venting tube.
Extra Slot	A location at the top of a rear incubator tower allowing a check plate to be stored.
File Link	A definition for transferring result files to a host using any valid OS/2 command for transferring files.
Filter Case	Device in the end module which holds up to 8 filters. A sticker identifies its part number and serial number.

Filter Strip	A device which holds the wavelength filter and a sticker with the wavelength written on it.
Fluid Connector	Revolving device on the front of the external pump station which connects the wash fluid container to the external pump station.
Front Tower Entry Module	Incubator with 5 slots at ambient temperature in the entry module.
Front Tower Inc.	Incubator with 5 temperature-controlled slots at the front of the module.
Height Mover Tool	Tool allowing manual movement of an incubator tower, entry lift or dispenser under power-fail conditions.
Host	Logical device to which the ML F.A.M.E. software transmits result files, i.e. one physical host can run two applications, one responsible for result archiving, the other for reporting. If the user software has to send result files to both applications in different ways, they will be defined as two hosts, say two logical devices. Two documentation jobs must be defined, one for each logical device.
Host Computer	Central collection station for all data, e.g. host other PC. PC to which test results are sent.
Incomplete Plate	An MTP not wholly filled with samples.
Incubation Slot	Short form: Slot. A single chamber within an incubator tower which accommodates a single MTP.
Incubator Check Plate	An MTP-sized device containing a thermometer used to verify incubator tower temperatures.
Incubator Entry Module	Short form: Incubator Entry or Inc./Entry. Incubator in the entry module with 5 ambient temperature slots (front tower) and 5 temperature-controlled slots (rear tower).
Incubator Incubator Module 1	Short form: Incubator 1 or Inc.1. Incubator with two 5 slot temperature-controlled towers (front and rear). Exists only in 16/30 and 24/30 instrument configurations.
Incubator Incubator Module 2	Short form: Incubator 2 or Inc.2. Incubator with two 5 slot temperature-controlled towers (front and rear).
Incubator Tower	Device with 5 incubation slots, either all at ambient temperature or all temperature-controlled.
Instrument Function	A functional element of the instrument, e.g. dispenser, washer, photometer, main shuttle, incubator slot. Different instrument configurations contain different numbers of instrument functions.
Instrument Package	Package into which all modules, the chassis and the shipping kit are packed.
Instrument Shutdown	A controlled, stepwise closing of the ML F.A.M.E. instrument including optional maintenance macros.
Interface Connector	The RS232 connector for connecting the computer to the ML F.A.M.E. instrument.
Keep Empty Wells	A well in a plate that serves no function in a test, i.e. no reagents are dispensed into it and no measurements made on it.
Keyboard Buffer	Keyboard memory.
Kit Lot No.	Production batch number of a test kit.
LAN	Local Area Network.
LAN-Station	Any computer/instrument connected to the LAN.
Layout	Rules for placement of controls, standards, samples, blanks etc. in the MTP.

LLD	Liquid level detection.
LOAD BUTTON	A button on the instrument, the pressing of which, will initiate the processing of a single MTP or an entry stack (loaded onto the entry lift).
LOADING	Refers to the date and time at which an MTP was loaded into the instrument.
LOADING ORDER	List of expected tests and test series with restrictions given by the operator: start times, position of wash solutions.
LOCKING DEVICE	Device which locks the reagent drawer while the dispensing head is in the reagent drawer.
LOCK STATUS	The state of availability of an instrument function for use in runs. Can be either “locked” (not available for use) or “unlocked” (available for use). Instrument functions may become locked due to an error or a fault.
LOGIN	Act of gaining access to the ML F.A.M.E. software with the related access rights via user name and password (Operator: *“user name”*).
LOGOUT	Act of departing from the program.
LOT NO.	Production batch number of a test kit or parts thereof.
MAINS CONNECTOR	An electrical socket on the instrument into which the mains electricity supply is connected.
MAIN SHUTTLE	Device which moves MTPs from module to module including the possibility to read the MTP barcode.
MAIN SHUTTLE RAIL	Device that guides the main shuttle from module to module.
MAINS SWITCH	An electrical switch on the instrument which connects/disconnects the instrument to/from the mains electricity supply.
MANIFOLD	Removable part of washer that aspirates fluid from the MTP and dispenses the wash fluid into the MTP.
MANIFOLD HOLDER	Component to which the manifold is attached.
MANIPULATION POSITION	Position in the exit stack allowing the removal of one MTP for further external processing.
M CODE	The current method security code of a method.
MENU BAR	An area at the top of a window that displays all the menus available in that window.
METHOD	A compendium of all necessary definitions (layout, test processing) for a test execution and documentation.
MIXER	Function that shakes the MTP horizontally in a lengthwise direction (performed by the module transport).
MODULE	Functional unit of the Summit Processor instrument.
MODULE TRANSPORT	Part which moves an MTP from the main shuttle into the module.
MTP	Microplate.
MTP BARCODE	See Plate Barcode.
MTP BARCODE READER	The barcode scanner that reads the barcode on the MTP for identification purposes.
MTP TRANSPORTER	Device that carries the MTP along the main shuttle.

MW	The optical density (OD) of a well measured by the photometer using the measurement wavelength.
OD	Optical density, absorbance.
***Summit Processor* 16/20**	Instrument configuration consisting of: 16 reagent positions 20 incubation slots (4 modules).
***Summit Processor* 16/30**	Instrument configuration consisting of: 16 reagent positions 30 incubation slots (5 modules).
***Summit Processor* 24/20**	Instrument configuration consisting of: 24 reagent positions 20 incubation slots (5 modules).
***Summit Processor* 24/30**	Instrument configuration consisting of: 24 reagent positions 30 incubation slots (6 modules).
ML F.A.M.E.	Microlab F.A.M.E.. Refers to the actual instrument.
ML F.A.M.E. Database	The database where all ML F.A.M.E. data (methods test results, device pre-settings, etc.) is stored.
ML F.A.M.E. Operator	Actual logged-in user (identical to actual user) operating the ML F.A.M.E. or ML F.A.M.E. Workstation, ML F.A.M.E. software. See also Login.
ML F.A.M.E. Software	General name of the software package.
ML F.A.M.E. Workstation	General name for the personal computer running the Microlab F.A.M.E. software package.
Parameter	Substance to be detected.
Parked Position	Hole in top of reagent container into which a disposable syringe is placed before the container is loaded into the reagent drawer.
Pause Button	A button which when pressed, causes an immediate stop of all moving instrument parts.
PC	Personal Computer (ML F.A.M.E. Workstation without software).
Photometer	Device which measures the optical density or transmission of MTP wells.
Photometer Check Plate	A special device the same size as an MTP used for checking the photometer.
Plan Window	The Plan window is displayed after a successful schedule (or simulated schedule) in the Work List Manager window and displays a graphical representation on the schedule.
Plate	Synonymous for microplate (MTP).
Plate Barcode	Short form: Barcode. The barcode attached to the microplate. Used for plate and method identification.
Plate Barcode Reader	Device which identifies barcodes on the plates.
Plate Fork	A tool allowing an MTP to be manually removed from an incubation slot in case of power fail.

Plunger	The inner part of the disposable syringe. Moves up and down inside the disposable tip/barrel.
P/N	Part Number.
Processing Status	Short form: Test Status. A flag that indicates at which point in the processing sequence a test is, e.g. Processed, Aborted, etc.
Raw Data	Raw OD values from a test.
Read Right	An access right which allows a user to view specific data in the user software.
Reagent	Conjugate, substrate or stop solution used in the reagent container.
Reagent Barcode Label	A barcode label designed to fit in the barcode recess of a reagent container.
Reagent Barcode Label Set	Set of 52 reagent barcode labels supplied with instrument.
Reagent Barcode Reader	The barcode scanner which reads the reagent container barcodes.
Reagent Container	Vessel which holds the reagent liquid.
Reagent Container Cap	Lid which closes the reagent container when not in the instrument.
Reagent Container Carousel	Removable device to which up to 8 reagent containers can be attached.
Reagent Container System	Reagent container, barcode label and disposable syringe together.
Reagent Drawer End Module	Short form: Drawer/End or End. Drawer in the end module containing a reagent carousel with max. 8 reagent containers.
Reagent Drawer Washer/Disp. Module 1	Short form: Drawer 1. Drawer in the washer/disp. module 1containing a reagent carousel with max. 8 reagent containers.
Reagent Drawer Washer/Disp. Module 2	Short form: Drawer 2. Drawer in the washer/disp. module 2 which contains a reagent carousel with max. 8 reagent containers. Exists only in 24/20 and 24/30 instrument configurations.
Rear Tower	Incubator with 5 temperature-controlled slots. Located in the rear of the module.
Redocument	The action of repeating all documentation jobs associated with a test, i.e. after a test has already been documented.
Registration Priority	A precedence level that determines which priority of trace message is recorded.
Release	The action of releasing a processed test for documentation.
Release Switch	Electrical switch which detects the presence of a user's hand on the reagent drawer handle.
Replica	Number of repeats of samples.
Residual Volume	The volume of fluid in the bottom of a reagent container that cannot be aspirated.
Result File	A temporary store of test result data. An ASCII file in which test results are stored after documentation.
Result File Format	Definition of the ASCII format of a result file with respect to the user programmable parts (documentation format).
Rinse Fluid	Fluid used to clean the tubings and manifold of the washer (normally distilled water).
Run	Execution of an ML F.A.M.E. work list.
Run Status	Gives information on the status of a test, i.e., Running, Processed and Documented.

RW	The optical density (OD) of a well measured by the photometer using the reference wavelength.
Sample	Specimen to be analyzed.
Sample and Reagent Addition Monitoring (SRAM)	A procedure used to determine the correct dispensing of samples or reagents (when reagents or samples are pre-treated with dye) using a photometric read step. The resulting data can be checked when processing is completed.
Service Container	A reagent container without a syringe used for performing special maintenance and error handling procedures (i.e. automatic syringe deposit).
Service Position	A recess in the top of a reagent container into which the cap is placed before the container is placed in the reagent drawer.
Service Technician	Trained and authorized service engineer.
Shipping Kit	Package that contains all necessary instrument accessories.
Slot Door	Flap on the front of an incubation slot which closes off the slot during incubation of an MTP.
Soak Time	Parameter of a wash cycle. The time wash solution remains in the wells before the plate is emptied.
Spillage Tray	A receptacle placed under the manifold during its removal and fitting. Resides in the container stack door.
Stack	See Stack Type.
Stack Type	An entry stack configuration consisting of between 1 and 4 tests (method and kit lot). The basic loading unit from which a work list is defined.
Stop Solution	Type of reagent used to interrupt the color development of the substrate reaction. Term also used: Blocking Solution
Substitute Plug	Electrical plug which plugs into the washer dispenser module instead of the waste cap cable when this is not being used.
The System	The ***Summit Processor*** instrument together with the PC running the ***Summit Processor*** software (ML F.A.M.E. workstation) and the serial cable connecting the two together.
System Manager	Person responsible for administration of the user software.
System Trace	A file containing all system related messages and actions related to the Summit Processor, i.e. ML F.A.M.E. software, tests and wells.
Test	A maximum of one MTP with an associated method on the ***Summit Processor*** system.
Test Documentation Batch	Several tests with the same documentation format, which are sent to the same device (printer, host, etc.).
Test Header	General Information in a test result report giving method, kit lot, test no., etc.
Test Kit	A package containing all necessary components for one or several assays of a kind.
Test Locking	The action of temporarily blocking user access to a test if actions are planned or being undertaken on it.
Test No.	A unique sequential number which identifies a test (can be part of a barcode).
Test Result Report	A report displayed on the computer screen giving the results of a test.
Test Run	The same as a run.

Test Step	A single test processing step (e.g. incubate, dispense, wash) of a method test processing definition.
Test Trace	A file containing all messages and actions related to a specific test.
Trace Priority	A level of precedence which a trace message carries. Allows the user to select which priority messages to register/display.
Transparent Cover	Hinged transparent door on front of instrument that prevents dust and user's hands from entering main shuttle area during operation.
Transport System	All parts used to move plates into, within and out of the instrument except the module transports, e.g. entry lift, main shuttle, manipulation position.
User Manual Box	Slot in entry module door for holding user manual.
Warm Start	An instrument initialization procedure which is executed (by the user software) at start-up when a cold start is not necessary. Normally executed under error conditions.
Wash Channel 1 (..4)	One of four wash channels associated with washer 1 (channel 4 is used for rinse fluid).
Wash Channel 5 (..8)	One of four wash channels associated with washer 2 (channel 8 is used for rinse fluid). Exists only in 24/20 and 24/30 instrument configurations.
Wash Check Plate	An MTP used during the checking of the washer. Resides in the extra slot of incubator module 2.
Wash Container Cap	Lid which closes the wash fluid container (air vent is incorporated).
Wash Container Slot	One of four positions in the external pump station into which a wash fluid container is placed.
Wash Container Stand	Device which allows a wash fluid container to be stood on its side during filling.
Washer	Device that washes an MTP.
Washer in Washer/Disp. Module 1	Part of Washer/Disp. Module 1 that washes MTPs.
Washer in Washer/Disp. Module 2	Part of Washer/Disp. Module 2 that washes MTPs.
Washer Lift	Device that raises and lowers the washer manifold.
Wash Fluid	Fluid specified by or supplied by test kit manufacturer used for washing an MTP (in an ELISA test for example).
Wash Fluid Container	Vessel which holds either wash or rinse fluid.
Wash/Rinse Tubing	Tubing that connects between the external pump station and the washer/ dispenser module.
Wash Shell	A component that sits under the manifold allowing rinsing of the washer.
Waste Cap	Lid which closes the waste container when in use and also allows connection of the waste tube. Incorporates LLD measurement.
Waste Container	Holds waste fluids which have been aspirated by the manifold.
Water Separator	A reservoir that defoams waste fluids before pumping into waste container. Also used as a temporary waste fluid store while the waste container is being changed.
W/D	Washer/Dispenser.
Well	A single cavity in an MTP. An MTP comprises 96 wells.
Well Flag	A status flag that indicates the status of an individual well in a test.

WELL GROUP One or more wells addressed together. Well groups are defined by specifying, well abbreviations, CAg/Ag coating or by specifying the “well type used as...” parameter.

WELL TRACE A file containing all messages and actions related to a specific well in a test.

WELL TYPE Description of a well, containing name, abbreviation and “well type used as...“ definition.

WELL TYPE USED AS... Synonymous with functional well category. Defines well with different functions for evaluation in machine readable form.

WORK LIST MANAGER A window where the ML F.A.M.E. operator constructs work lists from predefined stack types. Here the work list can be scheduled giving access to the Plan window. With this window it is also possible to set the earliest starting time for the stack type, assign a kit lot to a stack and abort either an individual test or an entire run.

WRITE RIGHTS An access right which allows a user to view and edit specific data on the ML F.A.M.E..

Appendix 3 Frequently Asked Questions

A3.1 Introduction

This section contains a list of questions frequently ask of the technical support department and training course instructors.

As these issues have no particular place in the main text of this manual, they have been collected into this appendix.

While these questions and answers address specific issues they are not an absolute cause of a problem, it is possible for example that the cause of the problem could be different to the explanation listed. Therefore it is recommended to first try the solutions listed in the following text and if this does not help, proceed with normal technical support.

A3.1.1 Updates

From time to time, an update of this appendix will be issued. If received, the updates should replace the entire appendix section of the user manual.

A3.2 Frequently Asked Questions

FAQ 1

Question	Answer
Global fluids can not be deleted from the database. An error message indicates that they are associated with an existing method, but no method can be found. How do I find this method ?	For all test results there is an entry in the data base for the method used and that method's security code, even if the method has been changed or deleted. These methods will not be visible when the list of methods is displayed in the Delete method selection dialog box. All test results for the particular method must be deleted before these global fluids can be deleted.

Appendix 4 Anomalies

Table of Contents

A4.1 - Introduction.....250
A4.2 - Anomalies during Run 250
A4.3 - Anomalies without Instrument Running 250

A4.1 Introduction

This appendix lists the known anomalies which still exist in the ML F.A.M.E. User Software and have not yet been eliminated.

A4.2 Anomalies during Run

ANOMALY-ID	DESCRIPTION	WORK-AROUND SOLUTION
887	The user ignores a waiting load plate dialog. It starts to beep, and the title bar is highlighted red. The user clicks on the dialog box with the mouse to silence the sound. This user action also resets the timeout for the dialog. If the user continues to silence the sound in this way, the dialog box remains on the screen and the error message "plate aborted" does not appear. However, if he does eventually load the plate, it may be aborted on entering the instrument, as the other time parameters have been exceeded.	Do not click in the dialog box more than once. If the screen is left as it is, the user timeout occurs and the loading procedure for the expected plate will be aborted.
959	The provided *runende.at* and *runende.sp* program switche erroneously during data transfer via LAN from the AT_BARCO.999 file to AT_BARCO.000 instead of AT_BARCO.001. The Barcode file *.000 can not be read by the host.	**.A)** Contact Hamilton and order the new version E2.5 of *runende.at* / *runende.sp*. **.B)** Alternatively, delete the content of the barcode file directory (e.g. h:\transfer) and copy the following files from the Sunrise directory to the remote directory: register.ini regneu.ini In the barcode file remote directory, rename the copied files as follow: register.ini -> register.inf regneu.ini -> regneu.inf

A4.3 Anomalies without Instrument Running

ANOMALY-ID	DESCRIPTION	WORK-AROUND SOLUTION
900	While instrument status window is open (view temperature) and dialog "verification required within 14 days" is displayed, the user selects reset of instrument status and the instrument is switched off. A system error causes software shutdown.	Do not switch off the instrument under the above-mentioned conditions.

Appendix 5 Forms

This appendix containes the following forms:

- ❒ Maintenance log form: this is to be used for recording details of maintenance carried out on the ML F.A.M.E.
- ❒ Problem report form: this form is used to report any problems encountered with the system.
- ❒ Software and firmware installation records: this form is to be used to record of software installed on the ML F.A.M.E. workstation, i.e., OS/2 DB2/2 and the ML F.A.M.E. software.

Maintenance Log

Laboratory name:.....
Instrument configuration:.....
Instrument serial no.:.....

Manifold serial no.: 1=.....
2=.....
3=.....
4=.....

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily																															
Empty and clean waste container(s)																															
Clean reagent containers																															
Clean syringes																															
Weekly																															
Empty and clean waste container(s)																															
Clean reagent containers																															
Discard syringes																															
Clean wash shell(s)																															
Clean base below washer(s)																															
Clean instrument																															
Monthly																															
Empty and clean waste container(s)																															
Clean reagent containers																															
Discard syringes																															
Clean wash shell(s)																															
Clean base below washer(s)																															
Clean instrument																															
Clean manifold(s)																															
Empty and clean external water separator																															
Half-yearly Maintenance																															

Initial the appropriate box upon completion of each item

Review supervisor:.....

Month Year:...../.....

Problem Report Form

Error number (for internal use only):	Date:
Company:	Name:
User software version:	OS/2 version:
PC processor:	PC RAM:
PC Hard drive size/free space:	Time problem occurred:
Brief description:	
Symptom:	
❒ User software hangs ❒ System error, Abort ❒ System error, Continue ❒ Exit ❒ Database error	❒ Installation fault ❒ Initialization fault ❒ Maintenance fault ❒ Verification fault ❒ Processing fault ❒ Window/dialog box fault ❒ Print fault
❒ Instrument hangs ❒ Module fault	❒ ..... ❒ .....
Detailed description of problem:	
Attached: ❒ System trace ..... ❒ Test trace ..... ❒ Well trace ..... ❒ Other	

Please sign and return to your instrument supplier.
Date:
Signed:

Software Installation Record

Computer Serial No.: .....

Instrument Serial No.: .....

Original OS/2 Version: .....

Original DB2/2 Version: .....

User Software Version: .....

Installed by: ..... *Date:* .....

Update Version	Installed by	Date	Initials

Supervisor Check:

Firmware Installation Record

Computer Serial No.: .....

Instrument Serial No.: .....

Firmware Version: .....

Installed by: ..... *Date:* .....

Update Version	Installed by	Date	Initials

Supervisor Check:

6 News Letters

A6.1 Introduction

The purpose of this appendix is to collect the periodic news letters which give information to ML F.A.M.E. operators concerning many aspects of using the ML F.A.M.E.. These news letters are very importent to the operation of the ML F.A.M.E. and ML F.A.M.E. software and must be stored here.

Appendix 7 User Manual Update Information

A7.1 Modification List

Date of Change	Revision	Description of Change
04/99	02	This user manual is valid for software Version 2.0 or higher until an newer revision is released (or informed otherwise).

Appendix 8 Index

A

Access Level 237
Access Right 237
Access Rights 145
Action List 107, 237
Archive 237
Archiving Test Data 134
Aspirate Speed 98
Aspirating Needle 237
Aspiration Height 97
Assigning Control well types 31
ASTM Format 237

B

Barcode Maintenance 175
Barcode Mask 87, 237
  forbidden characters 87
  number of characters 87
  wildcard characters 87
Barcode Specifications 191
Barcodes
  plate 191
  reagent container 193
Base Time 237
Bottom Sweep 97
Bottom Wash 97

C

CAg/Ag Coating 92
CAg/Ag-Coating 237
Change Lock Status 139
Chassis 237
Chassis Expansion 237
Check Plate 237
Circuit Breaker Ratings 185
Cleaning Reagent Containers 74
Cold Start 237

Collision-Free Position 205
Competitive Test 237
Conjugate 237
Container Stack 237
Continuous Wash 97
Control 237

D

Database 133
Decontaminate 172
Device 237
Device Presettings 141
Dispense
  aspirate speed 34, 35
  dispense speed 34, 35
  dispense volume 34, 35
  wells 35
Dispense Menu 98
Dispense Only 96
Dispense Speed 98
Dispense Step
  aspirate speed 98
  dispense speed 98
  dispense volume 98
  reagent name 98
Dispense Volume 34, 35, 98, 189
Dispenser 237
Dispenser End Module 237
Dispenser Washer/Disp. Module 1 238
Dispenser Washer/Disp. Module 2 238
Dispensing Needle 238
Display Priority 238
Disposable Syringe 238
  parked position 119
Disposable Tip/Barrel 238
Document Test 238
Documentation 101
Documentation Definition 238
Documentation Editor 85, 101
Documentation Format 238
Documentation Job 102, 238
Documentation Jobs 28, 84
Download 140
Drop-down List 238

E

Edit Status 132

Editor 238
ELISA 238
End Module 8
  dispenser 8
  exit stack 9
  mixer 8
  photometer 8
Entry Lift 238
  Green light 124
  Orange light 124
  Signal Lights 124
Entry Module
  main functions of 5
  power supply 6
Entry Module Specifications 187
Entry Platform 238
Entry Section 238
Entry Stack 238
Error 131
Error Handling
  collision-free position 205
Error status 131
Evaluation Editor 85, 101
  documentation 101
  documentation jobs 102
  test documentation jobs 102
Exit Lift 238
Exit Plate 100
Exit Stack 9, 238
External Interface Settings 143
External Pump Station 238
External Water Separator 7, 238
Extra Slot 238

F

File Link 238
Filter
  measuring 35
  reference 36
Filter Case 238
Filter Strip 239
Fluid Connector 122, 239
Fluids 100
Front Tower Entry Module 239
Front Tower Inc. 239

G

General Instrument Specifications 184
Global Settings 142
Glossary 237

H

Height Mover Tool 239
Host 239
Host Computer 239

I

Incomplete Plate 239
Incubate Menu 95
Incubation
  heating up 96
  tolerance time 32, 34
Incubation Check Plate 239
Incubation Slot 239
Incubation Temperature 95
Incubation Time 96
Incubation Tolerance Time 96
Incubator Decontamination 181
  recommended interval 181
Incubator Entry Module 239
Incubator Incubator Module 1 239
Incubator Incubator Module 2 239
Incubator Module 6
Incubator temperature 138
Incubator Tower 239
Initialize 139
Inserting Reagent Carousels 120
Inserting Reagent Containers 119
Instrument Dimensions 185
Instrument Function 239
Instrument Package 239
Instrument Shutdown 239
Instrument Weight 185
Interface Connector 239

K

Keep Empty Wells 239
Kit Lot Number 239

L

LAN 239
Layout 239
Layout Editor 85
LLD 240
Load Button 240
Loading 240
Loading Order 240
Lock Status 240
Locking Device 240
Login 240
Logout 240
Lot No. 240

M

M Code 240
Main Shuttle 240
Main Shuttle Rail 240
Mains Connector 240
Mains Switch 240
Maintenance 169
    general items required 170
Maintenance Procedures 173
    Every Day 173
    Every Month 175
    Every Week 174
Maintenance Requirements 175
Manifold 240
Manifold Cleaning
    ultrasonic bath method 72
Manifold Cleaning Set 179
Manifold Holder 240
Manipulation Position 240
Measurement Wavelength 9
Measuring Filter 35
Measuring Filter Wavelength 100
Menu Bar 240
Method 240
Method Information dialog box 84
Method Management 103
    backup 103

restore 103
Method Security Code
M code 86
Method Verification 104
Methods 83
exiting of 103
organization of 84
overview 84
processing steps 95
test processing editor 94
Mix
mix time 35
Mix Intensity 100
Mix Menu 100
Mix Step
intensity 100
time 100
Mix Time 100
Mixer 240
Modification List 263
Module 240
Module Specifications 187
Module Transport 240
MTP 240
MTP Barcode 240
MTP Barcode Reader 240
MTP Transporter 240

N

Number of Wash Cycles 96

O

OD 241
Operating Temperature Range 186
Operator 241
Ordering Information 13
Organization of Methods 84

P

P/N 242
Parameter 241
Parked Position 241

Pause Button 241
PC 241
PC Requirements 196
  optional requirements 196
Photometer 8, 241
  filters 8
  measuring channels 8
  reference channel 8
Photometer filter wavelength(s) 99
Plan 107
Plate 241
Plate Barcode 241
  label dimensions 192
  symbology 192
Plate Barcodes 191
  code density, tolerance 193
  length of information 193
  positioning on plate 192
  print contrast 193
  print quality 192
Plate Configuration
  CAg/Ag coating 92
  strip direction 92
Plate Dimensions
  length 91
  plate height 91
  well depth 91
  well diameter 91
Plate Fork 241
Plate Height 91
Plate Layout 28, 84
  arranging samples
    filling direction 30
  replica direction 93
  replica number 30
  sample filling direction 93
  sample replica number 93
Plate Layout Definition 90
Plate Layout Editor 90
Plate Layout Window
  samples menu 93
Plate Length 91
Plate Loading Window 109
Plate Wash 96
Plunger 242
Power Supply 6
Power Supply Specifications 184
Prepare for Service 139
Prepare Plate Menu 95
Preparing Reagents 119
Processed 131
Processing Status 242
Processing Steps 28, 84, 95
Pump Power 97

R

Raw Data 242
Read Menu 100
Read Right 242
Read Step
  measuring filter wavelength 100
  reference filter wavelength 100
Reagent 242
  stability time 33
Reagent Barcode Label 242
Reagent Barcode Label Set 242
Reagent Barcode Reader 242
Reagent Carousels
  inserting of 120
Reagent Container 242
Reagent Container Barcodes 193
  positioning of 194
Reagent Container Cap 242
Reagent Container Capacity 189
Reagent Container Carousel 119, 242
Reagent Container System 242
Reagent Containers
  cleaning of 74
  inserting of 119
Reagent Drawer 120
Reagent Drawer End Module 242
Reagent Drawer Washer/Disp. Module 1 242
Reagent Drawer Washer/Disp. Module 2 242
Reagent Name 98
Reagents
  preparing of 119
Rear Tower 242
Redocument 242
Reference Filter 36
Reference Filter Wavelength 100
Reference Wavelength 9, 243
Registration Priority 242
Re-Identify... 100
Release 242
Release Switch 242
Replica 242
Replica Direction 93
Replica Number 30
Residual Volume 242
Result File 242
Rinse Fluid 242
Run 242
RW 243

S

Sample 243
Sample and reagent addition monitoring... 98
Sample Filling Direction 93
Sample Replica Number 93
Samples Menu 93
Secondary Window 243
Service Container 243
Service Position 243
Service Technician 243
Set System Time 145
Shipping Kit 243
Simulated Instrument 142
Slot Door 243
Soak Time 96, 243
Software Presettings 142
Specifications
  barcodes 191
  circuit breaker ratings 185
  dispenser 189
    precision/accuracy 189
    reagent container carousel 189
    reagent container system 189
  end module 190
  entry module 187
    entry stack 187
    incubator towers 187
  exit stack 190
  general instrument specifications 184
  incubator module 187
    incubator towers 187
  instrument dimensions 185
  instrument weight 185
  mixer 190
  operating temperature range 186
  optional PC requirements 196
  PC requirements 196
  photometer 190
  plate barcode
    label dimensions 192
    symbology 192
  plate barcodes
    code density, tolerance 193
    length of information 193
    positioning on plate 192
    print contrast 193
    print quality 192
  power supply 184
  reagent container barcodes 193
    positioning of 194
  uninterruptable power supply 184
  UPS 184
  washer/dispenser module 188
    washer 188
Spillage Tray 180, 243

Stack 243
Stack Type 243
Steps Menu 95
Stop Solution 243
Strip Direction 92
Strip Wash 96
Substitute Plug 243
Summit Processor 16/20 241
Summit Processor 16/30 241
Summit Processor 24/20 241
Summit Processor 24/30 241
Summit Processor Database 241
Syringe
  volume of 189
System Manager 243
System Trace 135, 243

T

Technical Specifications 183
Test 243
Test Data
  managing of 133
Test Documentation Batch 243
Test Documentation Jobs 102
Test Header 243
Test Kit 243
Test Kit Package Insert 28
Test Locking 243
Test No. 243
Test Processing Editor 85, 94
  steps menu 95
Test Processing Steps
  dispense 98
  incubate 95
  incubation temperature 95
  incubation time 96
  incubation tolerance time 96
  mix 100
  prepare plate 95
  read 100
  wash 96
Test Report 243
Test Result Report Dialog Box 130
Test Results 129
  archiving of 134
  documenting a batch 133
  edit status 132
  overview 130
  storage of 133
  test status 131
Test Results Window 130
Test Run 243

Test Status 131
documented 131
Test Step 244
Test Trace 136, 244
The System 243
Trace 131, 140
Trace Messages 135
priority levels 135
Trace Priority 244
Trace Priority Levels 135
Trace Reports 135
Transparent Cover 244
Transport System 244
Troubleshooting and Error Handling 199
Type of measurement 99

U

Unchecked Methods 111
Uninterruptable Power Supply 184
Unstable Reagents 33
loading of 118
UPS 184
User Manual Box 244

V

Verification 148
View Configuration 141
View Filters 141

W

W/D 244
Warm Start 244
Wash Channel 1 (..4) 244
Wash Channel 5 (..8) 244
Wash Check Plate 244
Wash Container Cap 244
Wash Container Slot 244
Wash Container Stand 121, 244
Wash Fluid 244
Wash Fluid Container 121, 122, 244
Wash Menu 96
Wash Mode 96

Wash Options
bottom sweep 97
bottom wash 97
continuous wash 97
pump power 97
Wash Shell 244
cleaning of 72
Wash Solution Name 96
Wash Step
aspiration height 97
dispense only 96
number of wash cycles 96
plate wash 96
soak time 96
strip wash 96
wash mode 96
wash solution name 96
wash volume 96
Wash Volume 96
Wash/Rinse Tubing 244
Washer 244
Washer Decontamination 180
recommended interval 180
specific items required 180
Washer in Washer/Disp. Module 1 244
Washer in Washer/Disp. Module 2 244
Washer Lift 244
Washer Manifold
cleaning of 178
recommended cleaning intervals 178
Washer Manifold Cleaning
specific items required 179
Waste Cap 244
Waste Container 7, 244
Water Separator 244
Weekly Maintenance
specific items required for 176, 177, 178
Well 244
Well Depth 91
Well Diameter 91
Well Flag 244
Well Group 245
Well Trace 135, 136, 245
Well Type 245
Well Type Used As... 245
Well Types
keep empty 91
NC 91
PC 91
SA 91
Work List 106, 245
Write Right 245